drew heavily from the 2011 EPA Integrated Risk Information System (IRIS) Toxicological Review of TCE.[240] As noted in the 2014 work plan risk assessment,

> EPA/OPPT's work plan risk assessment for TCE is based on the hazard and dose-response information published in the toxicological review that the U.S. EPA's [IRIS] published in 2011. EPA/OPPT used the TCE IRIS assessment as the preferred data source for toxicity information. . . . The TCE IRIS assessment used a weight-of-evidence approach, the latest scientific information and physiologically-based pharmacokinetic (PBPK) modeling to develop hazard and dose-response assessments for TCE's carcinogenic and non-carcinogenic health effects. . .. Development of TCE's hazard and dose-response assessments considered the principles set forth by the various risk assessment guidelines issued by the National Research Council and the U.S. EPA.[241]

EPA clearly found the TCE IRIS assessment to be scientifically rigorous. EPA made this determination without the data underlying the key, peer-reviewed studies[242] used in the assessment being publicly available. EPA's proposed science rule would preclude the use of these studies, severely jeopardizing the fate of the proposed TCE bans and allowing high-risk uses of TCE to continue.

Proposed ban of methylene chloride for use in paint and coating removal under TSCA section 6(a)

EPA has proposed a ban on the use of methylene chloride in paint and coating removers.[243] Methylene chloride is associated with a number of hazardous health effects, including impaired visual and motor functions, respiratory irritation, headaches, nausea, and death.[244] The scientific basis for this proposed regulation is provided in the agency's 2014 risk assessment, *TSCA Work Plan Chemical Risk Assessment: Methylene Chloride: Paint Stripping Use*.[245] The work plan risk assessment for methylene chloride identified both cancer and non-cancer risks resulting from exposure to the use of methylene chloride in paint and coating

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[240] EPA, EPA/635/R-09/011F,"Toxicological Review of Trichloroethylene" (2011), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0199tr/0199tr.pdf.

[241] TCE Work Plan Risk Assessment at 65.

[242] The key studies used by EPA to derive the noncancer toxicity values for TCE are Deborah E. Keil et al., *Assessment of Trichloroethylene (TCE) Exposure in Murine Strains Genetically-Prone and Non-Prone to Develop Autoimmune Disease*, 44 J. Envtl. Sci. & Health, Part A 443 (2009); Margie M., Peden-Adams et al., *Developmental Immunotoxicity of Trichloroethylene (TCE): Studies in B6C3F1 Mice*, 41 J. Envtl. Sci. & Health, Part A 249 (2006), and Paula D. Johnson et al., *Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat*, 111 Envtl. Health Persp. 289 (2003). The key studies used by EPA to derive the cancer toxicity values for TCE are B. Charbotel et al., *Case-control Study on Renal Cell Cancer and Occupational Trichloroethylene Exposure in the Arve Valley (France)* (2006); and Ole Raaschou-Nielsen et al., *Cancer Risk Among Workers at Danish Companies Using Trichloroethylene: A Cohort Study*, 158 Am. J. Epidemiology 1182 (2003).

[243] 82 Fed. Reg. at 7464.

[244] *Id.* at 7468.

[245] EPA, Office of Chem. Safety & Pollution Prevention, EPA Doc. No. 740-R1-4003, TSCA Work Plan Chemical Risk Assessment: Methylene Chloride: Paint Stripping Use (2014) [hereinafter Methylene Chloride Work Plan Risk Assessment], https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf.

removers. As detailed in the work plan assessment, the proposed ban notes that liver toxicity and central nervous system effects are the most sensitive non-cancer endpoints for chronic and acute exposure, respectively.[246] Accordingly, these endpoints were used to evaluate the extent of risk resulting from exposure to methylene chloride using a margin of exposure (MOE) approach. The raw data underlying key studies used to derive the benchmark MOE for chronic exposure[247] and acute[248] exposures to methylene chloride are not publicly available. As with TCE, EPA's proposed regulation would preclude the agency from using these key studies to support the proposed rule to ban methylene chloride in paint and coating removers. The effect would be to severely jeopardize the finalization of this life-saving ban.

Final rule setting formaldehyde emission standards for composite wood products under TSCA title VI

In 2016, EPA issued a final rule establishing federal formaldehyde emission standards for composite wood products.[249] Formaldehyde exposure is associated with several adverse health impacts, including respiratory issues, eye and nose irritation, and lung and nasopharyngeal cancers.[250] As part of the rulemaking process, EPA conducted an economic analysis to determine which of several prospective regulatory actions would result in the largest net benefit after weighing the compliance costs that firms would incur and the public health benefits that would result from reduced formaldehyde exposure. [251] The monetary benefit that would result from the alleviation of adverse health outcomes associated with formaldehyde exposure was a core component of the economic analysis. Specifically, EPA calculated the annual estimated monetary benefits of avoided cases of eye irritation and nasopharyngeal cancer.

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[246] *Id.* at 115.

[247] K.D. Nitschke et al., *Methylene Chloride: A 2-Year Inhalation Toxicity and Oncogenicity Study in Rats* 11 Fundamental & Applied Toxicology 48 (1988).

[248] As discussed in the work plan chemical assessment for methylene chloride, EPA considered two different benchmark MOEs in its assessment of acute exposure risks—one derived from a 1-hour Spacecraft Maximum Allowable Concentration (SMAC) and the other from a California acute reference exposure level (REL). Methylene Chloride Work Plan Risk Assessment at 23. EPA preferred the SMAC-derived approach for reasons articulated in the work plan assessment. Raw data underlying many of the key studies used to derive the SMAC are not publicly available (Melvin E. Andersen et al., *Physiologically Based Pharmacokinetic Modeling with Dichloromethane, its Metabolite, Carbon Monoxide, and Blood Carboxyhemoglobin in Rats and Humans*, 108 Toxicology & Applied Pharmacology 14 (1991); Irma, Åstrand et al., *Exposure to Methylene Chloride: I. Its Concentration in Alveolar Air and Blood During Rest and Exercise and Its Metabolism*, 1 Scandinavian J. of Work, Env't & Health 78 (1975); G.D. DiVincenzo and & C.J. Kaplan, *Uptake, Metabolism, and Elimination of Methylene Chloride Vapor by Humans*, 59 Toxicology & Applied Pharmacology 130 (1981); Jack E. Peterson, *Modeling the Uptake, Metabolism and Excretion of Dichloromethane by Man*, 39 Am. Indus. Hygiene Ass'n J. 41 (1978); V.R. Putz et al., *A Comparative Study of the Effects of Carbon Monoxide and Methylene Chloride on Human Performance*, 2 J. Envtl. Pathology & Toxicology 97 (1979); Ronald S. Ratney et al., *In Vivo Conversion of Methylene Chloride to Carbon Monoxide*, 28 Archives of Envtl. Health: An Int'l J. 223 (1974); Richard D. Stewart et al., *Experimental Human Exposure to Methylene Chloride*, 25 Archives of Envtl. Health: An Int'l J. 342 (1972).

[249] 81 Fed. Reg. at 89,674.

[250] *Id.* at 89,677–78.

[251] EPA, Economic Analysis of the Formaldehyde Standards for Composite Wood Products Act Final Rule (2016) [hereinafter Formaldehyde Standards Econ. Analysis], Docket ID: EPA-HQ-OPPT-2016-0461-0037.

EPA relied on several robust, peer-reviewed studies to demonstrate the relationship between exposure to formaldehyde and these endpoints. For nasopharyngeal cancer, EPA referenced the highly regarded U.S. National Toxicology Program (NTP) Report on Carcinogens (RoC).[252] The U.S. NTP concluded that chronic exposure to formaldehyde increases risk of nasopharyngeal cancer as evidenced by several key human epidemiological studies.[253] For eye irritation, EPA relied on two epidemiological studies that examined residential exposure to formaldehyde.[254] Both these studies showed that the prevalence of eye irritation increases with heightened exposure to formaldehyde. The data underlying key, peer-reviewed studies that identify nasopharyngeal cancer and eye irritation resulting from formaldehyde exposure are not publicly available. EPA would have been forced ignore these studies were the proposed rule in place at the time the formaldehyde rule was developed. If the proposed rule is applied retrospectively, the formaldehyde rule will be at significant risk.

National Primary Drinking Water Regulation (NPDWR) for arsenic under the Safe Drinking Water Act (SDWA)

In 2001, EPA published a final rule, pursuant to its obligations under the Safe Drinking Water Act, establishing a new maximum contaminant level (MCL) for arsenic.[255] Ingestion of high levels of arsenic can result in death, and even low-level ingestion can lead to severe health impacts, including skin diseases.[256] As part of the rulemaking process, EPA requested that the National Research Council (NRC) review the agency's prior standards and risk assessments for arsenic as well as the available scientific data regarding the risks of arsenic exposure and ingestion.[257] Among the critical studies that the NRC analyzed were two epidemiological studies performed in the 1960s and 1970s that documented the relationship between arsenic in well water and skin diseases of an affected community in Taiwan.[258] The studies found that ingestion of high levels of arsenic through well water correlated to a higher likelihood of developing skin

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[252] Nat'l Toxicology Program, Formaldehyde, in Report on Carcinogens (RoC), 14th ed. 2016), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf; Nat'l Toxicology Program, *Final Report on Carcinogens Background Document for Formaldehyde* (Jan. 22, 2010) (used to develop the 2011 RoC review for formaldehyde).

[253] *Id.* at 1–2 (citing M. Hauptmann et al., *Mortality from Solid Cancers Among Workers in Formaldehyde Industries*, 159 Am. J. Epidemiology 1117 (2004); Allan Hildesheim et al., *Occupational Exposure to Wood, Formaldehyde, and Solvents and Risk of Nasopharyngeal Carcinoma*, 10 Cancer Epidemiology, Biomarkers & Prevention 1145 (2001); Thomas L. Vaughan et al., *Occupational Exposure to Formaldehyde and Wood Dust and Nasopharyngeal Carcinoma*, 57 Occupational & Envtl. Med. 376 (2000); Sheila West et al., *Non-viral Risk Factors for Nasopharyngeal Carcinoma in the Philippines: Results from a Case-Control Study*, 55 Int'l J. Cancer 722 (1993)).

[254] Formaldehyde Standards Econ. Analysis at 4-24 to -25 (citing Lawrence P. Hanrahan et al., *Formaldehyde Vapor in Mobile Homes: A Cross-Sectional Survey of Concentrations and Irritant Effects*, 74 Am. J. Pub. Health 1026 (1984); Kai-Shen Liu et al., *Irritant Effects of Formaldehyde Exposure in Mobile Homes*, 94 Envtl. Health Persp. 91 (1991)).

[255] 66 Fed. Reg. at 6976.

[256] CDC Fact Sheet, Arsenic – ToxFAQs (2007), https://www.atsdr.cdc.gov/toxfaqs/tfacts2.pdf.

[257] *See* Nat'l Research Council, *Arsenic in Drinking Water* (1999).

[258] *See generally id.* (citing Wen-Ping Tseng, *Effects and Dose-response Relationships of Skin Cancer and Blackfoot Disease with Arsenic*, 19 Envt'l Health Persp. 109 (1977); Wen-Ping Tseng et al., *Prevalence of Skin Cancer in an Endemic Area of Chronic Arsenicism in Taiwan*, 40 J. Nat'l Cancer Inst. 453 (1968)).

cancer and other skin diseases. NRC's report concluded that based on the available evidence, EPA's previous standard for arsenic was inadequate for protecting the public health.[259]

Following the NRC report, EPA finalized a MCL of 10 ppb for arsenic, which was based on the two epidemiological studies from Taiwan.[260] Both studies were peer reviewed, published in prestigious health and environmental journals, and have been cited numerous times by other researchers. Yet it is unlikely the data from these studies could be made publicly available, as the data are four to five decades old and include confidential individual health information. If applied retroactively, or if EPA re-evaluates the MCL for arsenic, the proposed rule would likely mean that EPA could not rely on these studies.

National Ambient Air Quality Standards (NAAQS) for oxides of nitrogen under the Clean Air Act (CAA)

In 2004, EPA awarded a grant to the University of Washington to study the effects of long-term air pollution on the development of cardiovascular disease. More than 6,000 patients across the nation participated in the 10-year study, called the Multi-Ethnic Study of Atherosclerosis Air Pollution Study ("MESA Air").[261] Results from the initial study showed that long-term exposure to oxides of nitrogen (NO_X) and fine particulate matter contributes to cardiovascular disease.[262] MESA Air was the first study to show the negative health effects of long-term exposure to air pollution. Through funding from EPA, the National Institutes of Health, and the Health Effects Institute, MESA Air research is ongoing.[263]

On April 18, 2018, EPA published a final rule maintaining the current NAAQS for NO_X.[264] As part of the rulemaking process, EPA published the *Integrated Science Assessment for Oxides of Nitrogen – Health Criteria*.[265] This assessment incorporated research from MESA Air, including research related to modeling and statistical techniques, and was relied on by EPA in maintaining the NAAQS for NO_X in 2018. Yet because confidential health data comprises most of the research's data, as well as other identifying data such as ages and addresses, it is extremely unlikely the underlying data can be made publicly available. Researchers seeking to use the study's data must formally request and be granted access to de-identified datasets and are prohibited from further distributing data received.[266] Despite initially funding the research, under the proposed rule, EPA would be restricted from relying on this research in future rulemakings.

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[259] *See* Nat'l Research Council, *Arsenic in Drinking Water* 8-9 (1999).
[260] EPA, Six-Year Review 2 Health Effects Assessment: Summary Report 34 (2009) (citing Tseng (1977); Tseng et al. (1968)), https://www.epa.gov/sites/production/files/2014-12/documents/822r09006.pdf.
[261] *Multi-Ethnic Study of Atherosclerosis (MESA) Air Study*, EPA (last visited Aug. 13, 2018), https://www.epa.gov/air-research/multi-ethnic-study-atherosclerosis-mesa-air-study.
[262] Dr. Wayne Cascio, *EPA's MESA Air Study Confirms that Air Pollution Contributes to the #1 Cause of Death in the U.S.*, The EPA Blog (May 25, 2016), https://blog.epa.gov/blog/2016/05/epa-mesa-air-study/.
[263] MESA AIR HOME, Univ. of Wash. Sch. of Pub. Health, Dep't of Envtl. & Occupational Health Servs. (last visited Aug. 13, 2018), http://deohs.washington.edu/mesaair/home.
[264] 83 Fed. Reg. at 17226.
[265] EPA, EPA/600/R-15/-68, Integrated Science Assessment for Oxides of Nitrogen—Health Criteria (2016).
[266] Memorandum from W. Craig Johnson, MESA Coordinating Ctr., on MESA Deidentified Dataset Distribution Policy Statement (Apr. 12, 2016), https://www.mesa-nhlbi.org/PublicDocs/MESA_DeidentifiedDataDistribution_PolicyStatement_04122016.pdf.

NAAQS for ozone under the CAA

In October of 2015, EPA strengthened the NAAQS for ozone,[267] which is the main component of smog. Ozone pollution is linked to asthma and other respiratory health problems, and it is particularly dangerous for children and the elderly. As part of the rulemaking process, EPA published the *Integrated Science Assessment for Ozone and Related Photochemical Oxidants* in 2013, which reviewed the available science to build the scientific basis for the NAAQS.[268] In the Integrated Science Assessment, EPA relied on recent epidemiological studies demonstrating the causal relationship between ozone and childhood asthma as well as other developmental effects.[269] These studies were peer-reviewed and are invaluable to ensuring that all people, and especially children and older adults, are protected from the dangerous impacts of smog. However, the studies include individual demographic and genetic data. It is unlikely the data could be made publicly available. Under the proposed rule, when EPA reviews the ozone NAAQS, the agency would likely be unable to rely on these studies.

Forthcoming proposed NPDWR for perchlorate in development under the SDWA

In 2011, EPA made a regulatory determination to develop a national primary drinking water regulation for perchlorate under the SDWA, based on the conclusion that "there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern."[270] Underlying this conclusion is a body of literature detailing the health risks associated with perchlorate, namely the chemical's interference with normal thyroid function by inhibiting uptake of iodide into the thyroid gland. Iodide is essential to making thyroid hormones that regulate the body's metabolism and orchestrate fetal and infant brain development. In its determination, EPA cited a study by Michael Zimmermann, which reviews the adverse effects that iodine deficiency has on children's health.[271]

Currently EPA is using peer-reviewed studies[272] to develop the dose-response model central to deriving the maximum contaminant level goal (MCLG) for perchlorate in drinking water. These studies demonstrate that perchlorate exposure during pregnancy results in low

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[267] 80 Fed. Reg. at 65292.
[268] EPA, EPA/600/R-10/076F, Integrated Science Assessment for Ozone and Related Photochemical Oxidants (2013), https://www.momscleanairforce.org/wp-content/uploads/2015/05/Ozone-2013-ISA-Executive-Summary.pdf.
[269] *See, e.g.*, Muhammad T. Salam et al., *Roles of Arginase Variants, Atopy, and Ozone in Childhood Asthma*, 123 J. of Allergy & Clinical Immunology 596 (2009); Talat Islam et al., Glutathione-S-transferase (GST) P1, GSTM1, *Exercise, Ozone, and Asthma Incidence in School Children*, 64 Thorax 197 (2009).
[270] 77 Fed. Reg. at 7762.
[271] *Id.* at 7763 (citing Michael Zimmerman, *Iodine Deficiency*, 30 Endocrine Reviews 376 (2009)).
[272] EPA, Post-Meeting Peer Review Summary Report: External Peer Review for EPA's *Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water* (Mar. 2018), https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0439-0012, Docket ID: EPA-HQ-OW-2016-0439-0012.

maternal level of the thyroid hormone T4 leading to neurodevelopmental problems in children.[273] As with the Zimmermann study, the data underlying these studies are not publicly available. Under EPA's Proposal, the agency would be unlikely to rely on these studies putting at risk both the 2011 regulatory determination itself and EPA's ongoing work to develop the perchlorate NPDWR.

Future regulatory action on PFOA and PFOS under the SDWA and CERCLA

In May 2018, EPA announced that the agency will begin the process of developing, under the SDWA, maximum contaminant levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), in addition to designating these chemicals as "hazardous substances," possibly under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[274]

EPA developed health advisories for PFOA and PFOS in 2016. The supplementary documents[275] provided with these advisories detail the various sources of evidence that EPA considered in its characterization of the health impacts of PFOA and PFOS. Among the sources of health effect information was the C8 Health Project,[276] a community-wide assessment of approximately 69,000 individuals living in or near Parkersburg, West Virginia, that was mandated as part of a lawsuit following a major release of PFOA from the DuPont Washington Works production plant into the area's drinking water. Based on this data set and other relevant studies, the researchers leading the C8 Health Project concluded that there was a probable link between PFOA exposure and several harmful health effects, including thyroid disease, ulcerative colitis, kidney cancer, and testicular cancer.[277]

The presiding judge sealed the data from the C8 Health Project to protect participant privacy. [278] Under EPA's proposed rule, when the Agency is developing regulations for PFOA—as it intends to do in the near future—it would not consider publications from the C8 Health

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[273] Martjin Finken, et al., *Maternal Hypothyroxinemia in Early Pregnancy Predicts Reduced Performance in Reaction Time Tests in 5- to 6-Year-Old Offspring*, 98 J Clin Endocinol Metab, 1417 (2013). ; Korevaar et al., *Association of Maternal Thyroid Function During Early Pregnancy with Offspring IQ and Brain Morphology in Childhood: A Population-Based Prospective Cohort Study* 4 Lancet Diabetes & Endocrinology 35 (2016); Victor J. Pop et al., *Low maternal free thyroxine concentrations during early pregnancy are associated with impaired psychomotor development in infancy*, 50 Clinical Endocrinology 149 (1999); Victor J. Pop et al., *Maternal hypothyroxinaemia during early pregnancy and subsequent child development: a 3-year follow-up study* 59 Clinical Endocrinology 282 (2003); F. Vermiglio et al., *Attention deficit and hyperactivity disorders in the offspring of mothers exposed to mild-moderate iodine deficiency: a possible novel iodine deficiency disorder in developed countries*, 89 J. Clinical Endocrinology & Metabolism 6054 (2004).

[274] Press Release, EPA, In Case You Missed It: "EPA Chief Vows that Clean Drinking Water is National Priority" (May 22, 2018), https://www.epa.gov/newsreleases/case-you-missed-it-epa-chief-vows-clean-drinking-water-national-priority.

[275] EPA, EPA-822-R16-003, Health Effects Support Document for Perfluorooctanoic Acid (PFOA) (2016); EPA, EPA-822-R16-002, Health Effects Support Document for Perfluorooctane Sulfonate (PFOS) (2016).

[276] Frisbee, et al., *The C8 Health Project: Design, Methods, and Participants*, 117 Envtl. Health Persp. 1873 (2009), https://ehp.niehs.nih.gov/wp-content/uploads/117/12/ehp.0800379.pdf.

[277] C8 Science Panel, *The Science Panel Website*, http://www.c8sciencepanel.org/index.html (last updated Jan. 4, 2017).

[278] Frisbee et al., at 1876.

Project because the raw underlying data are not publicly available. In failing to consider such crucial case studies, EPA would be ignoring best available science, thereby undermining its own attempt to protect Americans from emerging health threats such as PFOA and PFOS.

c) Prominent scientists and leaders in public health agree that this Proposal would harm science-based public health protections.

Leading experts in public health, science, and environmental policy agree that the proposed rule would have far-reaching, detrimental impacts on public health and would constrain EPA's decision-making capabilities. By limiting the scientific studies that EPA may consider, the proposed rule would lead to less effective environmental policies and weaker public health protections. Experts have said the following:

- "[The proposed rule] will threaten the lives of real people." – Commissioners of the Minnesota Pollution Control Agency and Department of Health[279]
- "If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim." – John P. A. Ioannidis, C.F. Rehnborg Chair in Disease Prevention at Stanford University[280]
- "It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them. . . . Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes." – Editors of *Science* family of journals, *Nature, Public Library of Science* journals, *Proceedings of the National Academic of Sciences*, and *Cell*.[281]
- "Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits. . . . [the proposed rule] could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts." – Members of the Science Advisory Board[282]
- "[The proposed rule] would prevent the best science from informing policy decisions and result in weaker health safeguards." – Harold P. Wimmer, National President and CEO of the American Lung Association[283]

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[279] Letter from John Linc Stine, Comm'r, Minn. Pollution Control Agency, & Jan Malcolm, Comm'r, Minn. Dep't of Health, to E. Scott Pruitt, Adm'r, EPA (May 15, 2018), http://www.documentcloud.org/documents/4465265-MPCA-MDH-Joint-Letter-to-EPA-Science.html#document/p1.

[280] John P.A. Ioannidis, *All Science Should Inform Policy and Regulation*, 15 PLoS Med. 5 (2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576.

[281] Jeremy Berg et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, 360 Science (2018), http://science.sciencemag.org/content/360/6388/eaau0116?utm_campaign=toc_sci-mag_2018-05-03&et_rid=296581013&et_cid=2008556.

[282] Memorandum from Alison Cullen, Chair of SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to the Members of the Chartered SAB and SAB Liaisons (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[283] Press Release, Am. Lung Ass'n, American Lung Association Strongly Opposes EPA's Proposed Rule to Limit Critical Health Science (Apr. 24, 2018), http://www.lung.org/about-us/media/press-releases/epa-propose-limit-health-science.html.

- "If [the proposed rule] had been in effect 20 years ago, the nation might have forgone programs that are preventing over 50,000 premature deaths each year." – Environmental Protection Network[284]
- "[The proposed rule] would greatly weaken EPA's ability to comprehensively consider the scientific evidence across the full array of health effects studies. This would negatively impact EPA public protections that reduce levels of lead, harmful chemicals, and fine particle pollution, among others." – 985 scientists in a joint letter to Administrator Pruitt[285]
- "[The proposed rule] would severely hamstring the agency when it comes to developing and enforcing public health rules by limiting the kinds of research the EPA can use in crafting rules." – Union of Concerned Scientists[286]
- "[Administrator] Pruitt is moving to rid the EPA of the science needed for effective regulation. . . . Its potential impact goes well beyond the EPA's regulatory effectiveness to the underlying role of science in American society." – Dr. Bernard Goldstein, Professor Emeritus of Environmental and Occupational Health at the University of Pittsburgh and former EPA Assistant Administrator for Research and Development.[287]

Additionally, when the U.S. House of Representatives passed similar legislation in 2017, H.R. 1430, numerous professional organizations raised concerns about the implications of the proposed legislation.[288] The Environmental Data & Governance Institute (EDGI) found that:

> A bill that provided genuine provisions for public data access and usability, and did not focus on mandating the reproducibility of studies and on prohibiting the use of any data that could not be divulged to the general public in its entirety, would not be expected to hamper the EPA in a significant way. EDGI's analysis of H.R. 1430 shows that it does not achieve its stated goals. Instead, our research shows that H.R. 1430 would not promote transparency and that its passage would instead block the EPA from using the data it needs to fulfill its mission of protecting public health and the environment.[289]

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[284] Memorandum from Envtl. Prot. Network on Preliminary Assessment of Pruitt's Proposed Regulation to Restrict EPA's Use of Sound Science 2 (Apr. 26, 2018), https://docs.wixstatic.com/ugd/4868e0_8bbc47f8b66848e4a60503d4dd3a9e72.pdf.

[285] Letter from 985 Scientists to E. Scott Pruitt, Adm'r, EPA (Apr. 23, 2018), https://s3.amazonaws.com/ucs-documents/science-and-democracy/secret-science-letter-4-23-2018.pdf.

[285] Press Release, Union of Concerned Scientists, Scientists Oppose Pruitt's Research Restrictions (Apr. 23, 2018), https://www.ucsusa.org/news/press-release/scientists-oppose-new-pruitt-restrictions#.WwM1Mu4vyUl.

[286] Press Release, Union of Concerned Scientists, Scientists Oppose Pruitt's Research Restrictions (Apr. 23, 2018), https://www.ucsusa.org/news/press-release/scientists-oppose-new-pruitt-restrictions#.WwM1Mu4vyUl.

[287] Bernard Goldstein, *Why the EPA's 'Secret Science' Proposal Alarms Public Health Experts*, The Conversation (May 18, 2018, 6:40 AM), https://theconversation.com/why-the-epas-secret-science-proposal-alarms-public-health-experts-96000.

[288] *See* Vivian Underhill et al., Envtl. Data & Governance Initiative, Public Protections Under Threat at the EPA: Examining Safeguards and Programs that Would Have Been Blocked by H.R. 1430 (2017), https://envirodatagov.org/wp-content/uploads/2017/03/Public-Protections-under-Threat-at-the-EPA.pdf; Jon Sperl & Amy Petz, Cong. Budget Office, H.R. 1430: Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (2017).

[289] *See* Vivian Underhill et al., Envtl. Data & Governance Initiative, Public Protections Under Threat at the EPA: Examining Safeguards and Programs that Would Have Been Blocked by H.R. 1430 18 (2017), https://envirodatagov.org/wp-content/uploads/2017/03/Public-Protections-under-Threat-at-the-EPA.pdf.

D. EPA's Policy Rationales for its Proposal are Arbitrary and Capricious

1. EPA arbitrarily fails to provide a reasoned explanation for why the proposed rule is needed.

In essence, EPA's proposed regulation is a solution in search of a problem—a problem that does not exist. The administrative record for the Proposal fails to show that the Agency's past regulatory decisions inappropriately relied on scientific information of questionable value. In fact, EPA fails to point to a single example of a case in which, in developing regulations, EPA relied upon a study or studies later found to be questionable or invalid. Having failed to address this foundational question, EPA also misses the questions that would build on that—even if EPA actually had used invalid science in some instance, EPA would still have to ask whether the underlying data for that study had been made publicly available, and if not, if the problems with the study could have been avoided through having made the data publicly available.

The Proposal neither acknowledges the mechanisms EPA already uses to ensure the integrity of science in decision-making nor establishes that there is a problem that the Proposal is needed to solve. The reality is that both Congress and EPA have established an array of mechanisms and safeguards over the last five decades to ensure that the Agency's decisions are grounded in best available science. These mechanisms include review of agency science and decisions by EPA's scientific advisory boards, including the Science Advisory Board (SAB), the Clean Air Scientific Advisory Committee, Board of Scientific Counselors, the Science Advisory Committee on Chemicals, and the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel[290]—a process that a work group of the SAB recently described as a "rigorous review process that goes beyond the typical journal peer review procedures,"[291] and that the National Research Council recognized as playing an "important role in helping EPA to ensure the credibility and quality of . . . science-based decisions."[292] The Proposal also ignores EPA's use of independent peer review processes to evaluate certain studies used in regulatory decisions;[293] the use of transparent literature surveys that are themselves subject to peer review

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[290] *See* 42 U.S.C. § 4365 (establishing the Science Advisory Board and requiring that EPA seek its review of, among other things, certain rulemakings under the Clean Air Act, Federal Water Pollution Control Act, Resource Conservation and Recovery Act, Noise Control Act, Toxic Substances Control Act, and Safe Drinking Water Act); 42 U.S.C. § 7409 (requiring the Clean Air Scientific Advisory Committee to advise EPA on matters relating to the National Ambient Air Quality Standards); 7 U.S.C. § 136w (requiring EPA to seek comments from the FIFRA Science Advisory Panel on certain rulemakings under FIFRA, and to seek advice on operating guidelines for scientific analyses by EPA that lead to actions carrying out FIFRA);

[291] Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science 4 (May 12, 2018) (observing that the Proposal "fails to mention that EPA has mechanisms for vetting science through several expert panels," including the SAB and others).

[292] Nat'l Research Council, Science for Environmental Protection: The Road Ahead 181 (2012) ("External advisory groups—including SAB, BOSC, and NACEPT—play an important role in helping EPA to ensure the credibility and quality of its scientific studies and science-based decisions.").

[293] *See, e.g.,* EPA Sci. and Tech. Policy Council, *Peer Review Handbook* xiii, 15 (4th ed. 2015) (noting that EPA has a "long-standing history of peer review" and providing for peer review of internally generated studies designated as "Influential Scientific Information" or "Highly Influential Scientific Assessments"); Nat'l Research Council,

and public comment, such as the Integrated Science Assessments (ISA) that inform the National Ambient Air Quality Standards;[294] and independent review of EPA science programs and risk assessment practices by authorities such as the National Research Council.[295] Major regulatory decisions—and the underlying scientific bases for those decisions—are also subject to public comment and judicial review, which serves as an important check on agency decisions that fail to properly account for the best available science.

Thanks to these multiple and overlapping safeguards, the quality of the science underlying EPA decisions is robust.[296] More to the point, there is no indication that EPA science suffers from the so-called "replication crisis" that the Proposal identifies as the principal reason for requiring the public disclosure of underlying data or models for studies used in EPA decisions.[297] It is telling that the sources EPA cites in support of its claims of a "replication crisis"[298] call into question its existence[299] and in many instances promote solutions that do not involve access to underlying data[300]—such as looking at cumulative evidence using a variety of methods instead of over-emphasizing the results of a single study.[301] It is even more telling that

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Science for Environmental Protection: The Road Ahead 180 (2012) ("In rule-making processes that rely on extensive reviews of scientific information, EPA generally imposes a strong preference for reliance on published, peer-reviewed studies. The agency's peer review policy states that 'peer review of all scientific and technical information that is intended to inform or support Agency decisions is encouraged and expected.'").

[294] *See* EPA, EPA/600/R-15/067, *Preamble to the Integrated Science Assessments* 5-25 (2015) (describing the steps EPA undertakes in preparing an Integrated Science Assessment, including extensive and transparent compilation and screening of relevant literature; public comment and independent review by the CASAC; and EPA's application of recognized frameworks in evaluating public health causation relationships).

[295] *See*, e.g., Nat'l Research Council, *Review of EPA's Integrated Risk Information System (IRIS) Process* 3 (2014) (describing the charge of the authoring committee as encompassing a review of recent changes to EPA's IRIS program as well as to "review current methods for evidence-based reviews and recommend approaches for weighing scientific evidence for chemical hazard and dose-response assessments."); Nat'l Research Council, Science for Environmental Protection: The Road Ahead at x (explaining that EPA asked authoring committee "to assess independently the overall capabilities of the agency to develop, obtain, and use the best available scientific and technologic information and tools to meet persistent, emerging, and future mission challenges and opportunities").

[296] *See* Nat'l Research Council, Science for Environmental Protection: The Road Ahead at 13 ("For over 40 years, EPA has been a national and world leader in addressing the scientific and engineering challenges of protecting the environment and human health."); Wendy Wagner, *Science in Regulation: A Study of Agency Decisionmaking Approaches* 29 (2013) (describing EPA's NAAQS review process as "exemplary" and a "five-star process for incorporating science into regulatory policy").

[297] 83 Fed. Reg. at 18770.

[298] It is additionally unclear what EPA means by "replication crisis," and EPA appears to be misusing the term, as the source it cites to describes a "reproducibility crisis," Marcus R. Munafò et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1 (2017), and another source details how "[a]s the movement to examine and enhance the reliability of research expands, it is important to note that some of its basic terms—reproducibility, replicability, reliability, robustness, and generalizability—are not standardized," Steven N. Goodman et al., *What Does Research Reproducibility Mean?*, 8 Sci. Translation Med. 1 (2016).

[299] Munafò et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1 (2017) ("Whether 'crisis' is the appropriate term to describe the current state or trajectory of science is debatable. . . . ")

[300] *See, e.g.*, Marcia McNutt, *Reproducibility*, 343 Science 229 (2014) ("[J]ournals can only do so much to assure readers of the validity of the studies they publish. The ultimate responsibility lies with authors to be completely open with their methods, all of their findings, and the possible pitfalls that could invalidate their conclusions.").

[301] John P.A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PLoS Med. 0696, 0700–01 (2005) ("Second, most research questions are addressed by many teams, and it is misleading to emphasize the statistically significant findings of any single team. What matters is the totality of the evidence.").

the Proposal identifies *no* EPA actions that have been called into question because the science underlying those actions cannot be validated or replicated. In any event, the Proposal does not require replication of studies and only limits the cumulative evidence and context in which to interpret any given study—only hampering EPA's reliance on more robust scientific findings even if such a crisis were to exist.[302]

In addition, numerous independent reviews of EPA's science-based actions by the courts, as well as the consistency with which the Agency has solicited and relied on the advice and approval of its external Science Advisory Board committees have added to the credibility of EPA's decisions. The Proposal provides no information supporting the notion that the overarching processes of EPA assessment of relevant scientific studies and subsequent peer review of such assessments, as well risk and policy assessments that EPA has developed and improved over time, are in any way insufficient to address the concerns that are allegedly the main focus of the proposal.

EPA's failure to identify a problem or inadequacy that new regulations are needed to address is not only arbitrary—it is also contrary to the directive of E.O. 12866 which states that:

> [f]ederal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. [303]

E.O. 12866 further directs each agency to "identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." [304] Before proceeding any further with this proposal, EPA should clearly identify the problem it is trying to solve, provide evidence that there is, in fact, a problem, and allow for public comment on whether a problem exists that could be addressed through EPA regulation.

This is not to say that EPA's use of science cannot be improved or strengthened—of course continued improvement is always desirable. But to improve upon current practices it is necessary to identify what is deficient, why, how it can be corrected and the potential effects of such deficiency and any proposed changes to practice. EPA does none of these.

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[302] Marcus R. Munafò & George Davey Smith, *Repeating Experiments Is Not Enough*, 553 Nature 399, 399–400 (2018), https://www.nature.com/articles/d41586-018-01023-3#ref-CR3 (noting that "[i]f a study is skewed and replications recapitulate that approach, findings will be consistently incorrect or biased" and suggesting that instead, "an essential protection against flawed ideas is triangulation," or "the strategic use of multiple approaches to address one question").

[303] Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

[304] *Id.*

2. EPA arbitrarily fails to offer a reasoned explanation for its departure from existing policies that broadly require the agency to consider all available scientific information when undertaking rulemakings.

In addition to the statutes discussed in Section I.B.3 that require EPA to use the best available science when making regulatory decisions, a number of EPA's own policies embed this requirement as well. By arbitrarily limiting the science EPA considers when making regulatory decisions, the Proposal contravenes these policies, injuring the scientific integrity of EPA's actions. As discussed in more detail in Section II.E because EPA is changing course from established policy, EPA must fully acknowledge and justify its decision, which it has failed to do in the Proposal.

EPA's own existing Scientific Integrity Policy states:

> To support a culture of scientific integrity within the Agency, this policy. . . [r]ecognizes . . . policy makers within the Agency weigh the best available science, along with additional factors such as practicality, economics, and societal impact, when making policy decisions.[305]

The Proposal conflicts with this policy by restricting what may be the best available science on a given topic from EPA's consideration solely because the underlying data cannot be made public. As described above, public availability of data is neither necessary nor sufficient to ensure that studies constitute "best available science." The Proposal does not acknowledge this departure from the agency's Scientific Integrity Policy, much less explain why such a departure is reasonable.

Likewise, the Proposal is in tension with EPA's Information Quality Guidelines, developed in response to OMB guidelines issued under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, which require EPA to ensure the objectivity of influential scientific information it disseminates by using "the best available science and supporting studies conducted in accordance with sound and objective scientific practices."[306] EPA considers information to be disseminated when EPA prepares and distributes information to support an Agency decision or regulation or when EPA distributes information in a way that suggests EPA agrees with it, that it supports EPA's viewpoint, or if in the distribution EPA proposes to use it to support or formulate a regulation or agency decision.[307] Thus, the Proposal conflicts with the Guidelines by restricting scientific studies that EPA may use to support regulations, which may cause it to disseminate other information to support its regulations that is not based on the best available science.

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[305] EPA, Scientific Integrity Policy 3-4.
[306] EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency 21-22 (2002), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf.
[307] *Id.* at 15-16.

EPA's Peer Review Handbook similarly acknowledges that "EPA strives to ensure that the scientific and technical bases of its decisions meet two important criteria: (1) they are based upon the best current knowledge from science, engineering, and other domains of technical expertise; and (2) they are credible."[308] EPA's Science Policy Council Handbook on Risk Characterization also requires reasonableness in the agency's risk assessments, which is achieved when "the characterization is based on the best available scientific information."[309] These policies clearly impact EPA's regulatory actions, and thus will be impacted by the Proposal. Yet EPA completely fails to analyze the impact the Proposal will have on its ability to comply with these policies and fails to explain why it is changing course or justify its decision to do so. Indeed, the Proposal fails to even acknowledge that the agency *is* changing positions.

3. EPA's Proposal arbitrarily fails to consider and deviates from best practices in scientific review, which support using a broad array of information, informed by a "weight of the evidence" approach, rather than arbitrarily excluding certain studies up front.

There is broad agreement in the scientific literature, reflected in EPA's own guidance, that a "weight of the evidence" approach is an optimal way to analyze and synthesize an array of scientific information in a decision-making context.[310] This approach, which is described in more detail below, calls for scientific assessments to be based on a broad array of studies—reflecting multiple lines of inquiry, where appropriate—each of which is carefully weighted based on various indicia of credibility. This careful and rigorous process is incompatible with the requirements of the Proposal, which would bar EPA from considering even highly credible, persuasive studies based solely on whether the underlying data is available. Yet the Proposal never acknowledges the conflict between its requirements and EPA's proven practices for scientific assessments, and never provides any good reasons for this change of course.

One prominent example of this "weight of the evidence" approach is contained in EPA's *Preamble to the Integrated Science Assessments*.[311] The *Integrated Science Assessments* are pollutant-specific reports that EPA produces as the scientific basis for establishing and updating

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[308] EPA, EPA Peer Review Handbook 4th Edition A-4 (Oct. 2015), https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.

[309] EPA, Sci. Policy Council, Risk Characterization Handbook 18 (2000), https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.

[310] *See, e.g.,* Matthew E. Bates, Olivia C. Massey, & Matthew D. Wood, *Weight-of-Evidence Concepts: Introduction and Application to Sediment Management* 5-8 (US Army Corps of Engineers ERDC/EL SR-18-1, Mar. 2018), http://www.dtic.mil/dtic/tr/fulltext/u2/1048843.pdf (reviewing literature on development of and best practices in weight-of-evidence assessment, and observing that "Within the US, the USEPA and its partner agencies use and recommend the use of WOE extensively."); *Cf.* John P.A. Ioannidis, *All science should inform policy and regulation,* PLOS Med 15:5 (May 3, 2018) ("Even the strongest science may have imperfections. In using scientific information for decision-making, it is essential to examine evidence in its totality, recognize its relative strengths and weaknesses, and make the best judgment based on what is available."); U.S. EPA. Preamble to the Integrated Science Assessments (ISA). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-15/067, 2015. *See also* EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* at 2 (June 2003) (describing EPA's guidance for carcinogen risk assessment and ecological risk assessment as additional examples of the agency's "weight-of-evidence" approach).

[311] EPA, Preamble to the Integrated Science Assessments (ISA) (EPA/600/R-15/067) (2015).

EPA's National Ambient Air Quality Standards (NAAQS), which establish health-based standards for critical air pollutants. The Integrated Science Assessments are intended to implement the Clean Air Act's directive to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health and welfare which may be expected from the presence of [a] pollutant in the ambient air."[312] These are some of the most consequential scientific evaluations that EPA performs, in terms of the health, environmental, and economic impacts of the resulting standards, and they must withstand the highest level of technical and legal scrutiny.[313] Thus, EPA uses the very best and most defensible scientific methods to produce them, which are described in the *Preamble to the Integrated Science Assessments*.

The *Preamble to the Integrated Science Assessments* is an "overview document outlining the basic steps and criteria used in developing the Integrated Science Assessments," which EPA references as a companion document to each Integrated Science Assessment.[314] As EPA explains, the "Preamble describes the process of searching the literature, selecting studies for consideration, evaluating study quality, synthesizing and integrating the evidence, and characterizing the evidence for public health and welfare impacts of criteria air pollutants."[315] It also "describes the five-level causal framework for evaluating weight of evidence and drawing scientific conclusions and causal judgments."[316] Central to this scientific assessment process is the understanding that evidence from all types of studies, such as animal studies, human observational studies (cohort, time series), controlled chamber studies, and exposure assessments, among others, must be evaluated and incorporated into final determinations of effects. No single study alone drives the final determinations of causality; rather, the weight of evidence from several lines of inquiry is critical.[317] This framework to evaluate all available science builds upon decades of accrued knowledge and thinking drawing from expertise across several disciplines, including evidence-based decision making.[318]

The Preamble states: "In its evaluation and integration of the scientific evidence on health or welfare effects of criteria pollutants, the U.S. EPA determines the weight of evidence in support of causation and characterizes the strength of any resulting causal classification."[319] The

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[312] *Learn About the ISAs*, EPA (quoting 42 U.S.C. § 7408(b)) (alteration in original), https://www.epa.gov/isa/learn-about-isas (last visited Aug. 14, 2018).

[313] *See Mississippi v. EPA*, 744 F.3d 1334, 1344-45 (D.C. Cir. 2013) (upholding EPA's use of the "weight of evidence" approach in setting NAAQS, saying EPA "evaluated the evidence as a whole through an 'integrative synthesis,' what it called a 'weight of evidence approach.' And appropriately so: one type of study might be useful for interpreting ambivalent results from another type, and though a new study does little besides confirm or quantify a previous finding, such incremental (and arguably duplicative) studies are valuable precisely because they confirm or quantify previous findings or otherwise decrease uncertainty") (citations omitted).

[314] EPA, Preamble to the Integrated Science Assessments. https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244 (last visited Aug. 14, 2018).

[315] *Id.*

[316] *Id.*

[317] *See* EPA, Preamble to the Integrated Science Assessments at 22.

[318] *See* Marcus R. Munafò & George Davey Smith, *Robust research needs many lines of evidence*, Nature (Jan. 23, 2018), https://www.nature.com/articles/d41586-018-01023-3#ref-CR3.

[319] EPA, Preamble to the Integrated Science Assessments at 18.

Preamble explains in further detail:

> In the ISA, the U.S. EPA assesses the body of relevant literature, building upon evidence available during previous NAAQS reviews, to draw conclusions on the causal relationships between relevant pollutant exposures and health or environmental effects. ISAs use a five-level hierarchy that classifies the weight of evidence for causation. This weight-of-evidence evaluation is based on the integration of findings from various lines of evidence from across health and environmental effect disciplines that are integrated into a qualitative statement about the overall weight of the evidence and causality.[320]

Similarly, section 26 of the Toxic Substances Control Act (TSCA) requires that decisions made under sections 4, 5, or 6 of the law must adhere to certain scientific standards including use of best available science and a weight of the scientific evidence approach.[321] In its final regulation, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, EPA defines weight of scientific evidence as:

> Weight of scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance. [322]

Systematic review in turn requires a full review of the body of scientific evidence available, where study quality is evaluated largely according to methodological design and not the degree to which underlying data are publicly available.[323] EPA's Proposal contravenes TSCA's requirements to apply a weight of the scientific evidence approach, as defined by the agency, by instating a process that, among other things, conflicts with applying a systematic review approach in the evaluation of chemicals under TSCA.

The Proposal's approach of preemptively barring studies based on the unavailability of data cannot be reconciled with EPA's detailed policies for scientific assessment.

> 4. EPA irrationally conflates scientific "validity" and "transparency" with data availability, incorrectly assuming that eliminating the use of studies without publicly available data will improve scientific validity and transparency.

In the preamble to the proposed rule, EPA states that the intent of the regulation is "to strengthen the transparency of EPA regulatory science."[324] Later in the preamble, EPA states: "[e]nhancing the transparency and validity of the scientific information relied upon by EPA

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[320] *Id.* at 22 (footnote omitted).
[321] 15 U.S.C. § 2625(h), (*i*).
[322] 40 C.F.R. § 702.33.
[323] Nat'l Research Council, Review of EPA's Integrated Risk Information System (IRIS) Process, https://www.nap.edu/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process.
[324] 83 Fed. Reg. at 18,768.

strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions."[325] EPA then leaps to the unexplained conclusion that barring the use of studies without publicly available data will enhance transparency and validity. EPA's assumption that data availability (or "transparency" in the form of data availability) ensures the use of valid science or its equivalent to using the best available science is manifestly incorrect, and hence provides an irrational basis for the proposed rule. In fact, neither data availability in particular, nor transparency in general, is equivalent to or a guarantee of "validity" in scientific studies.

a) EPA arbitrarily fails to explain why EPA's existing mechanisms are inadequate to ensure the scientific integrity of its actions.

The Proposal ignores both the available approaches embraced by the scientific community and the record of past EPA assessments, which reveal alternative methods for ensuring the credibility of potentially useful scientific studies. These alternatives include, but are not limited to: confidential sharing of data with independent research teams that are in a position to validate results; comparisons of research findings with the results of other peer-reviewed research efforts, including through meta-analyses and literature reviews that are designed to shed light on consistent findings across studies; and strong peer-review processes led by scientific journals, by EPA, or by advisory bodies such as the SAB.[326] Indeed, the SAB workgroup that examined the Proposal expressly noted its failure to acknowledge any of these mechanisms:

> The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods. For example, the Health Effects Institute (HEI) conducted a re-analysis of the influential Harvard Six Cities and American Cancer Society (ACS) epidemiologic studies and was able to replicate its findings and to assess the robustness of the findings via sensitivity analysis . . . in this particular case, an unusually rigorous form of peer review and independent reanalysis, coupled with many follow-up studies, has accomplished a measure of confidence in findings without public access to data and analytic methods. . . . The proposed rule fails to mention that EPA has mechanisms for vetting science through several expert panels . . . . For example, the EPA CASAC routinely reviews and evaluates epidemiologic and toxicological studies that are the basis for dose-response relationships used in risk and exposure assessments for air pollutants regulated under the National Ambient Air Quality Standards. Although such mechanisms do not typically engage in reanalysis of original data using the same methods as the original investigators, they do entail a rigorous review process that goes beyond the typical journal peer review procedures.[327]

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[325] *Id.* at 18,769.

[326] *See, e.g.,* Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine 2 (July 16, 2018) ("The National Academies have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data.").

[327] Memorandum from Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Alison Cullen, to Members of the Chartered SAB and SAB Liaisons 4 (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

EPA scientific assessments typically begin with expert staff identifying and assessing peer reviewed studies and studies published in reputable scientific journals. This includes examining the strengths and weaknesses of individual studies, including factors such as design, the reputation and past work of the researchers, quality assurance, methods and analyses. This is followed by a broader look to examine the consistency and coherence of the study with respect to the findings of similar study types across multiple studies, as well as a more integrated assessment of the weight-of-evidence that considers multiple lines of scientific evidence. The assessments are in turn peer reviewed by EPA scientific advisory committees as well as the public.[328] In certain exceptional cases, reanalysis by EPA or competent third party investigators can provide some additional credibility.

As the SAB workgroup that examined the Proposal noted, the record of EPA's treatment of the evidence in the case of two landmark fine particle epidemiology studies shows how scientific researchers and EPA used all of these approaches in examining the association between long-term exposures to fine particles and mortality. This effort began with Harvard's "Six Cities" study, reported in (Dockery et al., 1993).[329] The researchers initially sought to reproduce their initial findings using a data base with a much larger number of subjects and cities and did indeed reproduce those findings (Pope et al., 1995) (see below).[330] By 2009 enough new evidence had accumulated for EPA's integrated assessment for particulate matter to conclude that the number of large U.S. cohort studies, together with supporting evidence from other epidemiology and toxicological studies were sufficient to infer a causal relationship between long-term PM2.5 exposures and mortality and cardiovascular effects. This conclusion regarding causality (the strongest finding possible under the causality classification methodology[331]) based on these studies was endorsed by the external Clean Air Scientific Advisory Committee (CASAC), which noted: "The five-level classification of strength of evidence for causal inference has been systematically applied; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future ISAs."[332] (Samet, 2009). Thus, the link between particulate matter exposure and mortality that was observed in the Six Cities study has been vetted through multiple mechanisms that have confirmed the validity of the findings *without* public access to the underlying data—including extensive reanalysis using larger datasets with longer duration of follow up and different statistical methods; reproduction and corroboration with independent studies using distinct populations and methodologies; and rigorous external review by independent scientists.

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[328] *See, e.g.*, EPA, Preamble to the Integrated Science Assessments 3, Figure II, (2015) https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.

[329] Douglas W. Dockery et al., *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 New Eng. J. Med. 1753 (2003).

[330] C. Arden Pope, III et al., *Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults*, 151 Am. J. Respiratory & Critical Care Med. 669 (1995).

[331] The Preamble to the Integrated Science Assessments Sections describes the five-level hierarchy that classifies the weight of evidence for causation and methodology to make the determination, and "causal relationship" is the strongest finding.

[332] Letter from Dr. Jonathan M. Samet, Professor & Chair, Dep't of Preventive Med, Univ. of S. Cal., to Lisa P. Jackson, Adm'r, EPA (Nov. 2, 2009).

The Proposal says virtually nothing about the use of these existing mechanisms in EPA's current scientific assessment practices, or the level of confidence those mechanisms afford in EPA's regulatory science. Yet despite the proven track record of these mechanisms in assuring the validity of landmark studies such as the ACS and Six Cities studies, the Proposal would effectively reject their use and require EPA instead to exclude consideration of studies based on the sole criterion of public availability of underlying data. The Proposal's failure to explain this choice is arbitrary and capricious.

b) EPA arbitrarily equates data availability with valid science.

As discussed in detail in Section II.C.2, the absence of publicly available underlying data does not make the results of a study invalid or even suggest that the study is likely to be invalid. Nor has EPA presented evidence to suggest that studies with publicly available underlying data are more likely to represent strong science than studies without such data availability. As discussed in Section II.A.1, key reasons why researchers do not make data for some studies publicly available have nothing to do with scientific quality. Further, as discussed below and in the *Terminology* section, while reanalyzing study results using the same data is one way to help validate those results, it is neither the primary nor a sufficient way to do so. Hence, EPA's apparent conflation of data availability and best available science is not based on any evidence cited by EPA, is contrary to the evidence before EPA, and is simply arbitrary.

EPA's Preamble to the Integrated Science Assessments provides another discussion of how EPA evaluates study quality, and similarly, does not call out publicly available data:

> [T]he individual study quality is evaluated by considering the design, methods, conduct, and documentation of each study, but not the study results. This uniform approach aims to consider the strengths, limitations, and possible roles of chance, confounding, and other biases that may affect the interpretation of individual studies and the strength of inference from the results of the study.[333]

A statement by the American Statistical Association on p-Values: Context, Process, and Purpose further emphasizes the multiple considerations related to quality, stating "Researchers should bring many contextual factors into play to derive scientific inferences, including the design of a study, the quality of the measurements, the external evidence for the phenomenon under study, and the validity of assumptions that underlie the data analysis."[334] Similarly, the letter filed by the Presidents of the National Academies of Sciences, Engineering, and Medicine in this docket lists multiple reports conducted since 2007 that have examined EPA's scientific assessment processes and "that advise EPA on the scientific bases of regulatory decisions related to human health and the environment."[335] According to the NASEM Presidents,

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[333] EPA, Preamble to the Integrated Science Assessments at 7, https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.

[334] Ronald L. Wasserstein & Nicole A. Lazar, *The ASA's Statement on p-Values: Context, Process and Purpose*, 70:2 The American Statistician 129, 131 (2016).

[335] Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine 2 (July 16, 2018).

> These reports encourage EPA to consider *all available science in the rule-making process* and provide guidance about how the agency could be more transparent in describing how evidence is gathered and evaluated. . . . Individual study quality should be evaluated on the basis of information that is available in standard journal articles, such as the study design elements, analytical techniques, and statistical methods. Researchers may be contacted to answer questions about the conduct of the study or be asked to provide additional data. *If the study data are not available, their absence may affect how the study is rated and used in the analysis, but the study should not necessarily be eliminated from the assessment.*[336]

OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies* provide another important example of the distinction between information transparency and quality. Unlike the Proposal, which conflates transparency with quality, OMB's Guidelines encourage transparency as a means to obtain greater objectivity in data, but do not consider it an absolute requirement or the only means by which objectivity can be achieved. The Guidelines specifically provide that it is possible to verify the objectivity of information that cannot be made publicly available through other types of "robustness checks."[337]

As an example, the OMB Guidelines point to the Harvard Six Cities Study, where underlying data could not be made publicly available due to confidentiality concerns. In that case, the raw data was released only to researchers at the Health Effects Institute, who were bound to the same confidentiality requirements as the original researchers, and who were able to reanalyze and reproduce the study's results. [338]

c) Reanalyzing a study using publicly available data is not necessary to ensure valid science nor sufficient to ensure against invalid results.

To ensure the validity of scientific research, the scientific community relies most heavily upon peer review. In peer review, independent scientists with related expertise evaluate a study's quality using the types of factors discussed above. Studies used by EPA are often further evaluated by one of EPA's scientific advisory boards, such as the Clean Air Science Advisory Committee or the Science Advisory Board. These types of reviews do not depend on a study's data being made publicly available.

Making data available does allow independent researchers to try to reanalyze the same data and produce the same results. But reanalyzing a study is just one of many ways the scientific community ensures integrity, and it is not, in fact a widely used mechanism.[339]

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[336] *Id.* (emphasis added).

[337] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8,452, 8,460 (Feb. 22, 2002).

[338] *Id.* at 8,456.

[339] *See* John P.A. Ioannidis, *All science should inform policy and regulation*, 15 PLOS Med 1, 2 (May 3, 2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576 (However, we should recognize that

Reproducing study results using a different population or method is generally considered a stronger validation than simply reanalyzing the results using the same data, as it shows that the results hold across a different population.[340]

5. EPA arbitrarily attempts to bolster one element of scientific transparency, while ignoring significant other transparency-related concerns.

Another arbitrary aspect of this proposal is that EPA appears to assume that the only way to enhance transparency in regulatory science is to ensure that the underlying data and modeling for individual studies are publicly available. In fact, significant concerns have been raised about other non-public aspects of the modern scientific research and publication process that may undermine the accuracy of scientific results. For example, there are rising concerns about the increasing numbers of predatory pay-to-publish journals, which provide little-to-no guarantee of scientific integrity of their published studies.[341] Other areas of concern include undisclosed financial bias.[342] But rather than evaluating concerns related to transparency across the spectrum of peer-reviewed science, EPA has arbitrarily seized upon one narrow area. This area also happens to be a target of regulated industries, as discussed further in Section VII.

6. EPA's justification of the proposal is incoherent and lacks almost any evidentiary support.

Although as discussed above, EPA has not identified a problem with EPA's use of science, EPA may be assuming (without any basis of support) that it needs to strengthen the validity of the science EPA uses in rulemaking. If so, EPA then appears to leap to the conclusions (again without any supporting evidence) that the only way to strengthen the validity of the science is by enhancing transparency, that no other possible steps to enhancing integrity are worth considering, and that enhancing transparency means making underlying data and models publicly available. This is all before EPA even gets to its obviously illogical conclusion

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most of the raw data from past studies are not publicly available. In a random sample of the biomedical literature (2000–2014), none of 268 papers shared all of their raw data. Only one shared a full research protocol. The proportion of studies that have had all their raw data independently re-analyzed is probably less than one in a thousand. The number of studies that have been exactly replicated in new investigations is quite larger, but still a minority in most fields.") (citing Iqbal S, Wallach J, Khoury MJ, Schully S, Ioannidis JPA., *Reproducible research practices and transparency across the biomedical literature,* 14 PLoS Biol. 1 (2016) ("Replication studies were rare (n = 4), and only 16 studies had their data included in a subsequent systematic review or meta-analysis.")).

[340] *See, e.g.,* Comments of the International Society for Environmental Epidemiology on EPA's proposed rule on Strengthening Transparency in Regulatory Science Section 2 (EPA-HQ-OA2018-0259-0001), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1973 ("However, although data reanalysis has a role to play, ultimately, the key determination of the consistency of scientific evidence comes from replication, not reanalysis.") (note that ISEE uses the term "replicate" to mean what we have defined in these comments as "reproduce").

[341] *See* Gina Kolata, *Many Academics are Eager to Publish in Worthless Journals*, N.Y. Times (Oct. 30, 2017), https://www.nytimes.com/2017/10/30/science/predatory-journals-academics.html; *Publish and Don't Be Damned*, The Economist (June 23, 2018), https://www.economist.com/science-and-technology/2018/06/23/some-science-journals-that-claim-to-peer-review-papers-do-not-do-so.

[342] EPA, *Scientific Integrity Policy*, https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf (seeking to protect agency reliance on science from political interference, personal motivations, conflicts of interest, bias, etc.).

that threatening exclusion of studies without publicly available data will "increase access to dose response data and models underlying pivotal regulatory science," [343] rather than simply bar EPA from considering a vast universe of useful and rigorously vetted studies. The evidence cited by EPA in support of the need to strengthen science through its proposed approach is so vague and perfunctory that it is largely impossible even to tell which conclusions various sources are supposed to support. EPA's rationale for its data availability requirements consists of a few conclusory statements by EPA itself, a reference to "the replication crisis," and citations to a handful of articles and guidance issued by EPA and OMB. None of these provide a rational basis of support for the Proposal.

EPA begins by stating that the "proposed rule is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions."[344] While EPA is correct that it must disclose the basis and provide an adequate explanation for rulemaking (principles EPA manifestly fails to follow in this Proposal), it does not follow that these principles either require or support the quite specific notion that dose response data and models must be publicly available. Nor does EPA attempt to explain how these broadest of rulemaking principles support EPA's specific proposed approach here.

Next, EPA states that the proposal is "consistent with" two recent executive orders and OMB guidelines on information quality and agency information management. [345] One of the executive orders says nothing more than that environmental regulations should be "developed through transparent processes that employ the best available peer-reviewed science . . . . "[346] The other is targeted at eliminating regulations including those that are "unnecessary" and "ineffective," which, as our comments detail, the Proposal clearly would be.[347] While the OMB guidelines on information quality generally support transparency in science, they call for a far more nuanced approach than EPA proposes here and do not call for agencies to exclude studies for which underlying data is not available, as discussed above in section I.C. In fact, as discussed above, EPA's proposal unlawfully contravenes these guidelines.

EPA then states that the Proposal "builds upon" prior EPA actions in response to government-wide data access and sharing policies. [348] In support of this claim, EPA cites generally to five prior EPA policy documents related to science. EPA fails to point to a single statement, provision or requirement in any of these documents, however, as support for the specific approach proposed here. This is not surprising, as EPA's proposal to exclude studies with non-public data is actually a significant change from the prior policies, which supported balancing the interest in access to data with interests in privacy and confidentiality, as discussed in more detail in Section II.E. In fact, one of the documents cited by EPA, the *Plan to Increase Access to Results of EPA-Funded Scientific Research*, directly contradicts an apparent premise of

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[343] 83 Fed. Reg. at 18,770.
[344] 83 Fed. Reg. at 18,769.
[345] *Id.*
[346] Exec. Order No. 13,783, 82 Fed. Reg. 16,093, 16,093 (Mar. 31, 2017); *see also* discussion in Appendix A.
[347] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017); *see also* discussion in Appendix A.
[348] 83 Fed. Reg. at 18,770.

EPA's Proposal, stating: "Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications."[349] EPA ignores this contradiction altogether and provides no explanation whatsoever as to how the Proposal "applies concepts and lessons learned from [EPA's] ongoing implementation" of this plan, as EPA asserts.[350]

EPA also claims that the Proposal builds on the "experience of other federal agencies in this space."[351] In this case, EPA simply lists other federal agencies without referring to any policies, documents or actions by those agencies, except for one particular Census Bureau database that allows federal Census data to be shared securely. Obviously a bald uncited statement that other federal agencies have "experience in this space" is far too vague to allow meaningful comment by the public on EPA's rationale for its action, much less provide any support or rationale for the proposed policy. Further, the Census Bureau database cited is an example of how an agency can provide secure access to its own data, but it does nothing to explain or justify EPA's Proposal to exclude third party studies with nonpublic data from consideration in rulemaking. The U.S. Census Bureau operates the Federal Statistical Research Data Centers, which are secure facilities providing authorized access to restricted-use microdata for statistical purposes only. To gain access, researchers must obtain Census Bureau Special Sworn Status—passing a moderate risk background check and swearing to protect respondent confidentiality for life. This approach meets the U.S. Census Bureau's needs by allowing access to confidential information only to researchers whose proposals meet certain criteria, who go through a vetting process, and who agree to protect the information. Yet again, this is a structure designed to protect data collected by the government, not third parties, and there are substantial costs to this approach, which are borne by the Census Bureau. It is clearly not directly transferable to the context of the Proposal.[352] It is also unclear whether such a structure, even if it were practical (which it is not), would be sufficient to satisfy EPA's requirement to make data and models "publicly available."

Next, EPA vaguely refers to recommendations from third party advocates supporting "open science."[353] EPA does not specify, let alone discuss, those recommendations. EPA certainly does not explain how EPA's current use of science is inconsistent with any such recommendations or inadequate in light of them, or whether any of these third party organizations believe that studies with nonpublic data are insufficiently valid for use in rulemaking. Indeed, one of the organizations cited by EPA—the Bipartisan Policy Center

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[349] EPA, Plan to Increase Access to Results of EPA-Funded Scientific Research 4–5 (2016) (emphasis omitted), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.
[350] 83 Fed. Reg. at 18,770.
[351] *Id.*
[352] *See* Letter to Acting Administrator Wheeler from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine 3 (July 16, 2018). ("There are several differences in the confidential microdata collected from individuals and businesses by federal statistical agencies through surveys, versus data and results from the kinds of studies that are within the scope of the EPA proposed rule. These differences have important implications about making data publicly accessible. What works well in the federal statistical environment may not translate effectively to EPA, where stakeholders might be strongly motivated to discount study results that run counter to their regulatory preferences.").
[353] 83 Fed. Reg. at 18770.

("BPC")—filed a letter in this docket stating emphatically that "the proposed rule is not consistent with the BPC report in substance or intent. While the Science for Policy Project panel encouraged greater transparency and access to data, the report never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available."[354] Again, the policy documents cited in the footnote accompanying this statement generally undercut rather than support EPA's Proposal, as discussed in detail in Appendix A.

EPA also suggests that "these policies" (which policies it is unclear) "are informed by the policies recently adopted by some major scientific journals."[355] EPA does not cite any specific policies adopted by the journals named in the footnote, but it does not appear that any of those journals has determined that studies with nonpublic data are invalid and should not be relied upon or used. To the contrary, the editors of these journals issued a strong public statement affirming that "in not every case can all data be fully shared," that "the merits of studies relying on data that cannot be made publicly available can still be judged," and that "[i]t does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them…Excluding relevant studies simply because they do not meet rigorous transparency standards will adversely affect decision-making processes."[356] Again, however, EPA's failure to provide any specific information or citations in support of its conclusory statements make it impossible to meaningfully comment on the support for EPA's Proposal.

Further, EPA mentions "the replication crisis,"[357] but provides no information on the reality, seriousness, scope, implications, or causes of such a crisis. EPA fails to explain what it understands the "replication crisis" to be, much less how EPA's proposal might ameliorate it. It is not even clear whether EPA understands the meaning of the term "replication," as the agency fails to distinguish between "replicability" and "reproducibility," and uses both terms apparently interchangeably.[358] *See* earlier discussion of key terminology at page 9.

The proposed regulatory text provides, "[i]nformation is considered 'publicly available in a manner sufficient for independent validation' when it include the information necessary for the public to understand, assess, and *replicate* findings" and then lists "data" as the first type of information that may be included.[359] Yet "replicating findings" is essentially limited to laboratory animal and randomized controlled trials and does not capture the vast majority of human epidemiological studies. More importantly, replicating studies does not require access to underlying study data, but rather details regarding the methodological design. Further "reproducing" studies is generally viewed as a more informative and resource efficient approach to validation of research.

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[354] Letter from Jason Grumet, President of BPC to Administrator Scott Pruitt (May 22, 2018).
[355] *Id.*
[356] Jeremy Berg et al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018).
[357] *Id.*
[358] *Compare, e.g.*, 83 Fed. Reg. at 18774 (proposed rule requires information to be available "for the public to understand, assess, and replicate findings"), *and* 83 Fed. Reg. at 18770 (alluding to "replication crisis" as a basis for the need for the proposed rule), *with* 83 Fed. Reg. at 18772 (discussing an analysis purporting net benefits from the proposal due to "greater reproducibility"), *and* 83 Fed. Reg. at 18769 ("EPA must. . . ensure that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility.").
[359] 83 Fed. Reg. at 18773-74 (emphasis added).

Finally, to the extent that specific circumstances justify actually replicating a study, EPA fails to explain why it is necessary to make a study's underlying data broadly available to the public rather than employing a more secure approach that protects personal privacy. For example, to quell concerns about the validity of the American Cancer Society Cancer Prevention Study II (ACS CPSII) and the Harvard Six Cities Study—both seminal air pollution studies that are described earlier in these comments—an independent panel of Canadian and American scientists independently audited and reanalyzed them. Due to personal privacy concerns, the data was not made publicly available but was instead held in a restricted access data warehouse at the Health Effects Institute, an organization funded by both the automotive industry and EPA. The independent audit and reanalysis took three years and roughly one million dollars. It evaluated the consistency and accuracy of the data and then undertook a series of comprehensive analyses to test the robustness of the original findings and interpretations to alternative analytic approaches. The results of the independent analysis found resoundingly similar results for both studies.[360]

The results of this reanalysis suggest that routine assessment of quality indicators such as methodology, confounding and bias routinely evaluated in the peer review process are generally sufficient to confirm a study's validity. Further, while it plainly would be infeasible to undertake such an expensive and time-consuming reanalysis for the vast majority of studies, this example demonstrates that it is possible to undertake a reanalysis without making underlying data broadly available to the entire public. Yet EPA's proposed rule apparently would bar regulators from relying on these high quality and extensively vetted studies due to the fact that the underlying data was never made publicly available. EPA does not—and cannot—explain how a rule that would prohibit the agency from considering these seminal, high quality scientific studies comports with its goal of strengthening the agency's use of science in regulatory actions.

7. EPA has failed to explain why it has singled out dose response studies to be excluded if their underlying data and models are not publicly available, but has not similarly targeted any other types of studies commonly used by EPA.

EPA also has proposed to target the requirements for public availability specifically to the data and modeling underlying one specific subset of scientific research—dose response studies. EPA has provided no explanation or justification for targeting dose response studies in particular or for not including other types of studies or scientific information. EPA has not suggested that these studies are inherently less reliable than other studies, that they more

[360] For the Harvard Six cities study, the reanalysis results were 1.28 hazard ratio for mortality per 18.6 microgram per meter cube of PM2.5, in comparison to a hazard ratio of 1.26 found in the original study. For the ACS CPSII study, the reanalysis showed that for every 25.4 microgram per meter cube change in PM2.5 there was an associated hazard ratio for mortality of 1.18 (results of the independent reanalysis), as compared to the hazard Ratio of 1.17 reported by the original investigators. Daniel Krewski, et al., *Overview of the reanalysis of the Harvard six cities study and American Cancer Society study of particulate air pollution and mortality*, 66 J. Toxicology & Envtl. Health Part A 1507 (2003); Health Effects Inst., Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality (2000).

commonly fail to publicly disclose data and modeling information, that replication is more necessary for these studies than others, or any other conceivable reason. Absent any explanation from the agency, it is impossible to comment on the factual predicates for EPA's proposed decision, or the reasonableness of EPA's justification, except to state that it appears completely arbitrary in the absence of any rationale. *See, e.g., Transactive Corp., v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996) ("A long line of precedent has established that an agency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently.").

8. EPA arbitrarily failed to consider the implications of this proposal on interagency coordination.

Additionally, EPA arbitrarily failed to consider the far-reaching implications this Proposal could have on inter-agency coordination and consultation given that other agencies normally rely on research potentially excluded by the Proposal.[361] In the numerous environmental statutes that EPA cites, there are dozens of provisions that require EPA to coordinate or consult with other Federal entities—especially when implementing research programs and issuing information or guidelines.[362] The Proposal would almost certainly frustrate and impair this coordination and consultation, either by forcing EPA to ignore the science provided by other agencies or by severely restricting the science that EPA itself would be able to share with other agencies in these statutorily required processes. The Proposal arbitrarily ignores these potential impacts.

In addition to the many examples of statutorily required consultation that are identified in Appendix B, other federal agencies routinely incorporate and rely upon EPA science assessments in their own efforts to carry out their mandates to protect human health and safety. As with statutorily required consultations, the Proposal utterly fails to acknowledge or consider what impacts restricting EPA's own use of dose-response studies would have on the work of these other agencies. Indeed, there is no evidence that these other agencies were even permitted to comment on the Proposal as part of the usual process of interagency review.

Some selected examples of other federal agency programs that rely on EPA science include:

- The Food and Drug Administration (FDA) enforces tolerances established by EPA for pesticide chemical residues in human and animal foods under the Federal Insecticide,

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[361] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem.").

[362] *See* 42 U.S.C. §§ 7403, 7408(a), 7408(c), 7408(f), 7412 (Clean Air Act §§ 103, 108, 112); 33 U.S.C. §§ 1314. 1317(a)(7), 1345(d)(1) (Clean Water Act §§ 304, 307(a)(7), 404(d)(1)); 42 U.S.C. §§ 6907(a), 6911, 6912(a)(2)-(6), 6942(b), 6981(a) (Resource Conservation and Recovery Act §§ 1008(a), 2001, 2002(a)(2)-(6), 4002(b), 8001(a)); 7 U.S.C. §§ 136w-3, 136w(d), 136a-1(n)(2)-(3), 136(ll)(2), 136t(b), 136i-2(c) (Federal Insecticide, Fungicide, and Rodenticide Act §§ 2, 4, 11, 22, 25, 28); 15 U.S.C. §§ 2608(d), 2604(f)(5), 2604(h)(2)(B)(ii) (Toxic Substances Control Act); 42 U.S.C. § 300g-1 (b)(1)(D), 300g-1(d), 300j-13(a)(5), 300j-3d, 300j-19(b)(2)(A) (Safe Water Drinking Act). *See also* Appendix B: Table of Consultation Requirements.

Fungicide, and Rodenticide Act, including through a comprehensive pesticide residue monitoring program that tests for approximately 700 pesticide residues in both imported and domestic commodities.[363] To the extent the Proposal affects EPA's tolerances, the nature and effectiveness of FDA's own work to monitor for violations of those tolerances would be impacted.

- FDA also regulates contaminants in bottled water under the Federal Food, Drug and Cosmetics Act. Section 410 of the Act requires that FDA regulations for bottled water be issued in coordination with the effective date of National Primary Drinking Water Regulations issued under the Safe Drinking Water Act, and be no less protective of public health than those standards. If the Proposal impedes EPA's work to establish drinking water standards, this may affect FDA's own ability to justify protective bottled water standards.[364]
- In certain circumstances, FDA also coordinates with EPA to provide the public with information and advice on environmental contaminants in foods. For example, in 2017 FDA and EPA released a joint advisory on mercury hazards associated with the consumption of fish and shellfish, which was based in part on EPA's assessment of the "reference dose" or level of exposure that a person can experience over a lifetime without a risk of harm.[365] The Proposal could radically alter the science EPA would be permitted to consider in future such initiatives, and frustrate the ability of FDA and other agencies to coordinate effectively with EPA to develop joint advice and information.
- The Department of Housing and Urban Development is required by statute to assist EPA in assessing the extent of radon contamination in the United States and developing measures to avoid and reduce radon contamination.[366] HUD has also developed policies to require radon testing at properties receiving federal financing, which incorporate EPA radon standards.[367] To the extent the Proposal affects future EPA assessments of radon risks, the scope, cost and effectiveness of HUD radon programs could be affected as well.

9. EPA's proposal irrationally excludes proceedings that tend to benefit industry interests, even though these proceedings are far less transparent than the rulemakings EPA has targeted.

EPA's claims that it values transparency are clearly a pretext for eliminating "inconvenient," life-saving science from rulemakings that increase public health protection. Among other things, by excluding adjudications, permit proceedings, and certain rulemakings, EPA has excluded proceedings where EPA and industry regularly rely on nondisclosed information and where agency action in general, and particularly expeditious action, tends to

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[363] FDA, *Pesticide Residue Monitoring Program Questions and Answers, https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm583711.htm* (last visited Aug. 13, 2018).
[364] FDA, *Guidance for Industry: Bottled Water and Total Coliform and E. Coli; Small Entity Compliance Guide, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm206215.htm* (last visited Aug. 14, 2018).
[365] Advice About Eating Fish, From the Environmental Protection Agency and Food and Drug Administration; Revised Fish Advice; Availability, 82 Fed. Reg. 6572 (Jan. 19, 2017).
[366] *See* Pub. L. 100–628, title X, § 1091, Nov. 7, 1988, 102 Stat. 3283.
[367] *See* HUD, HUD Office of Multifamily Development Radon Policy, Notice H 2013-03 (Jan. 31, 2013), *available at https://www.hud.gov/sites/documents/13-03HSGN.PDF.*

favor industry. By limiting the proposal to "significant regulatory actions," the proposed rule would treat exactly the same study differently depending on whether it supports regulation or non-regulation in a particular context. The proposed rule will tend to exclude evidence when it supports a health-protective regulation that is costly to industry, but the proposed rule will then allow the use of the exact same evidence when the ultimate agency decision avoids regulation or deregulates industry activities or otherwise has low compliance costs. Thus, the Proposal is clearly shaped to favor industry interests, not to further transparency.

Specifically, EPA has chosen to limit the application of this Proposal to "significant regulatory actions" under E.O. 12866, and thus EPA does not extend this Proposal to adjudications, permit proceedings, or many less economically significant rulemakings.[368] In particular, EPA has effectively exempted the TSCA new chemicals program where industry seeks expeditious actions allowing market access and EPA regularly fails to disclose its own analyses and the studies and materials supporting those decisions, much less any underlying data. As explained below, in these proceedings industry seeks affirmative authorization from EPA to commercialize chemicals, so industry has a vested interest in expeditious government action.

EPA's decision to exempt these proceedings is particularly egregious because these proceedings are extraordinarily more opaque than the rulemakings EPA has targeted with this Proposal. In the TSCA new chemicals program, EPA often provides no meaningful opportunity for public review or comment before EPA takes action, and EPA regularly violates its existing statutory and regulatory obligations by disclosing almost none of its analyses or the information supporting its decisions to authorize the manufacture of new chemicals. Notably, much of the information at issue has never been peer-reviewed or subjected to nearly the level of public scrutiny as have the studies that EPA is trying to exclude from health-protective rulemakings under the proposed rule. EPA cannot credibly claim to pursue transparency with this Proposal while running certain programs as "black boxes" where little, if any, information is disclosed. To be clear, the problem is that EPA often does not disclose its own analyses or many of the underlying studies at all, much less underlying data; it is outrageous for EPA to then turn around and suggest that, in other contexts, disclosure of its analyses and the supporting peer-reviewed studies provides insufficient transparency.

As drafted, EPA's Proposal will not apply to EPA's New Chemicals Review Program under TSCA. TSCA § 5 governs EPA's review of "new chemical substance[s]," generally chemicals that have not previously been distributed in U.S. commerce.[369] By and large, no person may manufacture (defined to include import) a "new chemical substance" in the United States without providing EPA notice at least 90 days beforehand.[370] When a person submits a pre-manufacture notice (PMN), EPA must review the PMN and make one of three types of determinations under TSCA § 5(a)(3).[371] EPA then must take the actions required by the

[368] 83 Fed. Reg. at 18,771.
[369] *See* 15 U.S.C. §§ 2604, 2602(11).
[370] *Id.* § 2604(a)(1).
[371] *Id.* § 2604(a)(1)(B). Depending on the circumstances, instead of submitting a PMN, a person may seek to obtain one of several exemptions from the PMN process, such as the Test Marketing Exemption. The proceedings governing applications for these exemptions involve even less public disclosure than EPA's processing of PMNs. EPA's proposal will also not apply to the proceedings governing these exemptions.

relevant determination, and the person must comply with any applicable requirement imposed.[372] The person may not begin manufacturing the chemical substance until EPA has completed its review and made a determination. These proceedings do not qualify as significant regulatory actions under E.O. 12866, because EPA does not consider them rulemakings and because the regulation of chemicals that have not yet been introduced to the market generally will not be economically significant within the meaning of the E.O.

Because industry generally cannot manufacture a new chemical substance until EPA has completed its review, industry has a strong interest in expeditious action on PMNs. Nor is this idle speculation; industry commenters have repeatedly called for EPA to move more expeditiously.[373] Providing disclosure in these proceedings would likely, at a minimum, take additional time, and thus it seems likely that EPA has exempted these proceedings to serve industry's interest in hasty resolution.

Moreover, the New Chemicals Program is infinitely more opaque than the rulemakings EPA is currently targeting with its Proposal, often in direct violation of law. EPA does not make the public files for new chemicals electronically available, and when a person does obtain a copy of the public file from EPA, [374] the files generally reveal almost none of EPA's analyses supporting its decisions or the information submitted to support those decisions, with massive amounts of data redacted or concealed as Confidential Business Information (CBI). It's not a question of failing to disclose all the underlying data; EPA often fails to disclose the supporting studies or information at all.

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[372] *Id.*

[373] *See, e.g.*, Am. Coatings Ass'n Comment on New Chemicals Review Program 2 (Jan. 20,2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0068 ("We urge the Agency to expedite the process as much as possible, so that manufacturing is able to commence."), Docket ID: EPA-HQ-OPPT-2017-0585-0068; Am. Chemistry Council Comment on New Chemicals Review Program 7 (Jan. 19,2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0062 ("These delays underscore industry's continuing concerns that the section 5 program remains too slow . . . ."), Docket ID: EPA-HQ-OPPT-2017-0585-0062; U.S. Chamber of Commerce Comment on New Chemicals Review Program 3 (Jan. 19, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0057 ("[T]he Chamber believes that EPA should continue to strive to meet the 90-day goal in a timelier and more effective fashion . . . ."), Docket ID: EPA-HQ-OPPT-2017-0585-0057; Am. Petrol. Inst. Comment on New Chemicals Review Program 2 (Jan. 19, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0053 ("EPA should respond to a request for a Pre-Notice Consultation in a short timeframe—two to four days, rather than two to four weeks."), Docket ID: EPA-HQ-OPPT-2017-0585-0053; Int'l Fragrance Ass'n N. Am. Comment on New Chemicals Review Program 1 (Jan. 20, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0064 (identifying as a problem "review periods far exceeding 90 days – some exceeding a year"), Docket ID: EPA-HQ-OPPT-2017-0585-0064.

[374] As EDF has previously explained, EPA is already committing systematic procedural violations by failing to make the public files for new chemicals electronically available to the general public. Envtl. Def. Fund Comment on New Chemicals Review Program 23–26 (Jan. 20, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071, Docket ID: EPA-HQ-OPPT-2017-0585-0071. Under TSCA § 5(d), each Pre-manufacture Notice (PMN) "shall be made available, subject to section 14, for examination by interested persons." 15 U.S.C. § 2604(d)(1). EPA's implementing regulations provide that "[a]ll information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice," 40 C.F.R. § 720.95, and those public files are supposed to be "available in the electronic docket at http://www.regulations.gov." *Id.* § 700.17(b)(1). But EPA generally does not make the public files for PMNs electronically available.

As EDF detailed in prior comments and in various blog posts, EPA regularly conceals vast swathes of information in this program, including providing many blank documents identified as consisting of health and safety studies.[375] Notably, in this same context, industry commenters have urged EPA to take steps to accept data and information that will not be publicly disclosed or where EPA will only be provided with or make public industry-prepared summaries of the underlying data. *See, e.g.*, Comment submitted by Raleigh Davis, Assistant Direction, EHS, American Coatings Association (ACA), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0068 ("ACA strongly encourages EPA to develop as many of these [non-disclosure agreements] as possible."); Comment submitted by Jared Rothstein, Senior Manager, Regulatory Affairs, Society of Chemical Manufacturers & Affiliates (SOCMA), p.1 https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0049 ("EPA should accept the submission of robust summaries."). Thus, industry has expressed a desire for EPA to continue to operate the new chemicals program with limited disclosure, and thus far, EPA has acceded to that wish.

If EPA extended the rule articulated in proposed § 30.5 to the new chemicals program, it would seem that EPA would either have to make much of the information in the public files available *or* EPA would be precluded from using this information. 83 Fed. Reg. at 18.769 n.3 (stating that EPA is proposing to preclude itself from using such data in future regulatory actions). Without this information, EPA generally would not be able to find that the new chemical "is not likely to present an unreasonable risk of injury to health or the environment," the finding that allows unregulated manufacture of the chemical. *See* 15 U.S.C. § 2604(a)(3)(C). Notably, TSCA expressly provides a resolution when EPA has insufficient information, requiring that EPA regulate the chemical. *Id.* § 2604(a)(3)(B)(i), (e). When "the information available to [EPA] is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance; … [EPA] shall issue an order" regulating the chemical "to the extent necessary to protect against an unreasonable risk of injury to health or the environment." *Id.* 2604(e).Thus, excluding the information would require EPA to regulate the new chemicals before they could enter the market.

Thus, EPA's exclusion of the new chemicals program clearly favors industry, allowing industry to conceal information and evade regulation. In addition, EPA cannot rationally impose stringent new disclosure requirements that exclude extensive peer-reviewed, high-quality studies in some contexts while simultaneously authorizing the commercial distribution of new chemicals with almost no disclosure and no peer-review.

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[375] Envtl. Def. Fund Comment on New Chemicals Review Program 24-25, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071. For more detail, see EDF's series of blog posts on its finding in its our review of public files for nearly 70 new chemicals for which EPA made "not likely to present an unreasonable risk" determinations, *E.g.*, Stephanie Schwartz & Richard Dennison, *EPA's Appalling Failure to Provide Public Access to Public Data on TSCA New Chemicals*, EDF Health Blog (Jan. 24,2018), http://blogs.edf.org/health/2018/01/24/epas-appalling-failure-to-provide-public-access-to-public-data-on-tsca-new-chemicals/.

E. EPA's Proposal is Arbitrary Because it is Inconsistent With Long-Standing EPA and Federal Government Policies and Ongoing Efforts to Strengthen Science Quality in a Measured and Balanced Way through EPA's Existing Science Policies.

EPA claims throughout the Proposal that it is consistent with EPA and other federal government policies and approaches to transparency. However, a closer look reveals that the documents that EPA itself cites do not support the over-simplified and drastic approach taken by the Proposal. Federal government policies to promote data transparency have instead advocated a careful approach that balances the benefits of data disclosure with the costs and risks associated with it. Nowhere do they suggest that confidential information that cannot be made public is no longer valid for agency use. Instead, they aim to maximize the integrity and usability of data through data sharing when possible and practical—to enhance rather than hinder the ability of government agencies to achieve their missions. The Proposal is based on unsubstantiated claims that lack evidence, deviates from existing EPA and broader federal government policy without acknowledgement or explanation, and conflicts with leading research and policy proposals in this area— rendering the Proposal arbitrary and capricious.

Agencies are required to justify reversals in policy by addressing the existing record and reasons for why a change in policy is appropriate.[376] They must acknowledge the change and "show that there are good reasons for the new policy."[377] The agency must supply a reasoned analysis beyond which would be required in the absence of the old policy.[378] An agency may not "disregard contrary or inconvenient factual determinations that it made in the past."[379] EPA in the past took the position that:

> [EPA] does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the Federal courts have made clear that the EPA is not required to obtain or analyze the raw data in order to rely on such studies. If the EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.[380]

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[376] *FCC v. Fox Television Stations, Inc.* 556 U.S. 502, 515 (2009).

[377] *Id.*

[378] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42 (1983) ("[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").

[379] *FCC v. Fox Television Stations, Inc.* 556 U.S. 502, 537 (2009) (Kennedy, J. concurring).

[380] House of Representatives, Committee on Agriculture, *Hearing to Consider the Impacts of the Environmental Protection Agency's Actions on the Rural Economy* Serial No. 114-41, 82 (Feb. 11, 2016) (response to questions from Gina McCarthy, Administrator, EPA); *See also* Email from Nancy Beck to Justin Schwab and Richard Yamada (Mar. 5, 2018, 1:42:01 AM) (part of FOIA release to request by Union of Concerned Scientists citing EPA pesticide program documents from December 2016) (email flags language from EPA pesticide program documents: "To be clear, EPA continues to believe that the raw data should be made available for public inspection to ensure that EPA's assessments are as transparent as possible. While the EPA therefore strives to ensure that data underlying research it relies upon are accessible to the extent possible, it does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in

Thus, EPA in the past set forth a view diametrically opposed to the one it is taking now—in the past relying heavily on studies it would now be excluded from using. EPA previously recognized that there are other ways to validate scientific studies, such as through peer review, that do not require release of underlying data and its prior view rightly saw the danger in adopting a policy that would require EPA to make public underlying data.

EPA's current policies set forth standards of scientific integrity that involve use of the best scientific information available (see II.D.2), which the Proposal also now re-writes. While previously EPA took the view that all valid science (with proper quality control and assessment measures in place) should be considered as it sets standards, EPA now takes the position that it is more important to use only those studies where the underlying data and models are made available to the public, even if this compromises EPA's ability to use the best available science. EPA's existing open data policies recognize with exceptions and exemptions that as much as the pursuit of making data public is a worthy goal, there are competing interests. EPA has always taken the view that not releasing certain kinds of data to uphold these competing interests does not in fact compromise its scientific integrity or commitment to transparency—and the balance it strikes is the one most suitable to help its achieve its greater mission. The Proposal is arbitrary because EPA does not even acknowledge that it is now changing its view drastically and does not address the valid reasons underlying its prior policies or explain why they now merit changing.

1. Instead of providing a reasoned explanation for its change in policy, EPA wrongfully claims the Proposal is consistent with existing EPA, federal government, and third-party practices and policies.

As discussed further below in Section VIII.D, the footnotes of EPA's Proposal in many cases provide only vague references to policies and reports that purportedly support the Proposal, leaving the public to guess as to what EPA is referring and embark on a treasure hunt for the relevant item. But even where EPA provides specific citations, examination quickly reveals that frequently they do not fully support the propositions they accompany, and, when viewed in full context, provide evidence against the Proposal. Because EPA makes a series of conclusory statements provided with no explanation or reasoning that would help the reader understand why EPA interpreted the cited record to support the Proposal, the Proposal appears to be completely unsupported by evidence and explanation—rendering it arbitrary and capricious. A full documentation of the misrepresentations made in the footnotes of the Proposal is available in Appendix A and demonstrates that EPA is not able to substantiate its claims that the Proposal has been informed by or is consistent with the policies of EPA, other agencies, or other organizations.

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the public literature across agency programs without possessing underlying data and the federal courts (see Coalition of Battery Recyclers Association v. EPA, 604 F.3d 613 (D.C. Cir. 2010); American Trucking Associations v. EPA, 203 F.3d 355 (D.C. Cir. 2002)) have made clear that EPA is not required to obtain or analyze the raw data in order to rely on such studies. If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.").

EPA claims: "The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science."[381] The sentence is accompanied by a footnote listing a number of organizations, for most of them not providing reference to any specific policies, recommendations, or statements.[382]

One of these vague references points to the Administrative Conference of the United States' Science in the Administrative Process Project, without providing further detail. Assuming that EPA is referring to the Administrative Conference of the United States' *Recommendation 2013-3: Science in the Administrative Process*, Wendy Wagner, sole author of ACUS's final report *Science in Regulation: A Study of Agency Decisionmaking Approaches* and who served on the panel that produced the Bipartisan Policy Center's recommendations also cited by the Proposal has stated: "They don't adopt any of our recommendations, and they go in a direction that's completely opposite, completely different. . . . They don't adopt any of the recommendations of *any* of the sources they cite. I'm not sure why they cited them."[383] While ACUS recommends agencies increase transparency of how they rely on scientific information and strive to make data underlying scientific information publicly available, nowhere does it suggest that agencies should not consider or rely on studies where underlying data and models cannot be made publicly available, or that these circumstances make scientific information less valid. ACUS instead suggests that information be made publicly available "to reproduce or assess the agency's technical or scientific conclusions" "[c]onsistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines"[384] Moreover, ACUS acknowledges valid limitations on public disclosure of data such as legal protections for privacy, trade secrets, and confidential business information.[385] Thus, ACUS recommends data be made public only "[t]o the extent practicable and permitted by law and applicable policies."[386] Unlike the Proposal, the recommendation acknowledges that agencies may still use information where underlying data cannot be publicly disclosed, and suggest agencies "note that fact and explain why they used the results if they chose to do so."[387] It thus provides a much more nuanced policy recommendation than that outlined in the Proposal—which suggests EPA either find a way to make underlying data and models public, despite the numerous potential obstacles and concerns in doing so, or completely disregard the research study.

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[381] 83 Fed. Reg. at 18,770.

[382] 83 Fed. Reg. at 18,770. n. 10 ("These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data,* and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project").

[383] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 25, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.

[384] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process,* 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

[385] 78 Fed. Reg. 41,352, 41,358 n.12 (July 10, 2013).

[386] 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

[387] 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

EPA's claims that its Proposal is consistent with the policies of major science journals is similarly misleading.[388] EPA does not explain why the policies of scientific journals regarding the disclosure of data underlying their published studies *should* inform how an agency with a mission to protect human health and the environment uses research for regulatory actions. Additionally, these journals' policies provide exceptions for when privacy or other concerns do not allow for public sharing of data, and they never represent that this on its own weakens the validity of the research.[389] And, as discussed supra in Section I.B.2.a), the editors of these journals have specifically dismissed the Proposal.[390]

EPA wrongfully claims its policy is consistent with existing OMB and EPA policies, while failing to recognize that these polices—while advocating for more transparency—take a measured, nuanced approach to data disclosure.[391] EPA cannot finalize this policy without acknowledging and providing a reasoned explanation for its divergence from long-standing policy and without providing actual evidence that supports the Proposal, which it has not done. Prior policies recognize that government decision-making requires considering all scientific information, and legitimate limitations to data disclosure should not obstruct sound policy-making. EPA cannot rely on these documents to support the rule, leaving an inadequately thin record of evidence to support the Proposal, and must respond to policy rationales articulated in these documents as it now changes course.

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[388] 83 Fed. Reg. at 18,770 (EPA states that the policies and recommendations it considered were "informed by the policies recently adopted by some major scientific journals and cites to "related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature."); 83 Fed. Reg. at 18,771 n. 20 (citing "policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature" as potential mechanisms for compliance with Proposal).

[389] Taylor & Francis, *Data Sharing FAQs*, https://authorservices.taylorandfrancis.com/data-sharing-faqs/ (All our policies allow exceptions where data sharing violates protection of human subjects or other valid subject privacy concerns.) (last accessed Aug. 15, 2018); Elselvier, *Research Data Policy*, https://www.elsevier.com/about/our-business/policies/research-data (policy merely encourages when possible, rather than requires, data sharing: "Research data should be made available free of charge to all researchers wherever possible and with minimal reuse restrictions.") (last accessed Aug. 15, 2018); PLOS One, *Data Availability*, http://journals.plos.org/plosone/s/data-availability (allows exceptions to making data public "for ethical or legal reasons, e.g., public availability would compromise patient confidentiality or participant privacy" or present other threats) (last accessed Aug. 15, 2018); Springer Nature, *Research data policies FAQs*, https://group.springernature.com/gp/authors/research-data-policy/faqs/12327154 ("reasonable restrictions on data availability are permitted to protect human privacy, biosafety or respect reasonable terms of use for data obtained under license from third parties.") (last accessed Aug. 15, 2018). *See, also,* discussion in Appendix A.

[390] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

[391] EPA states: "This proposed rule is also consistent with . . . the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies* (the Guidelines) and OMB *Memorandum 13–13: Open Data Policy—Managing Information as an Asset*." 83 Fed. Reg. at 18,769-70. EPA says the Proposal "builds upon prior EPA actions in response to government wide data access and sharing policies," that it applies "concepts and lessons learned" from implementation of to the 2016 *Plan to Increase Access to Results of EPA-Funded Scientific Research*, 83 Fed. Reg. at 18,770, also citing to EPA *Open Government Plan 4.0*, *Open Data Implementation Plan*, *EPA's Scientific Integrity Policy*, and *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, 83 Fed. Reg. at 18,770 n. 8.

The *Plan to Increase Access to Results of EPA-Funded Scientific Research*, discussed supra at I.B.2.b), represents the view EPA has consistently espoused in the past, that when it can make data available without compromising other critical values, it does, but will not exclude information from its consideration when it cannot.[392]

EPA cites to its implementation of OMB's guidelines, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. These Guidelines note "[t]he mission of the EPA is to protect human health and safeguard the natural environment upon which life depends" and "[t]he collection, use, and dissemination of information of known and appropriate quality are integral to ensuring that EPA achieves its mission."[393] They thus highlight that the controls on data quality exist to allow EPA to meet its mission—unlike the Proposal, which changes EPA's existing view by placing transparency of data, apparently for its own sake even when unrelated to data quality, ahead of EPA's ability to achieve its mission. As explained above in Section I.C, the Proposal violates the Information Quality Act and these Guidelines.[394]

EPA disregards the careful approach to data disclosure outlined in OMB Memorandum M-13-13, *Open Data Policy-Managing Information as an Asset*, which requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities, and does not establish a policy of requiring agency data to be made public in order for the agency to be able to rely on it.[395] It recognizes that sharing agency data with the public can result in numerous benefits, but requires careful thought about privacy and confidentiality concerns. The memorandum establishes "a framework to help institutionalize the principles of effective information management at each stage of the information's life cycle to promote interoperability and openness," noting "[w]hether or not particular information can be made public, agencies can apply this framework to all information resources to promote efficiency and produce value."[396] It places consideration of privacy concerns at the forefront, saying "[a]gencies should exercise judgment before publicly distributing data residing in an existing system by weighing the value of openness against the cost of making those data public."[397] EPA has provided no indication that it has carefully weighed these costs and benefits.

Before agencies make data publicly available, OMB Memorandum M-13-13 requires that agencies "review the information collected or created for valid restrictions" such as legal, "privacy, confidentiality pledge, security, trade secret, contractual, or other valid restrictions to release."[398] OMB recognizes these restrictions "may affect the amount, type, form, and detail of

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[392] *See, also,* discussion in Appendix A.
[393] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA/260R-02-008)* 5 (Oct. 2002), https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.
[394] *See, also,* discussion in Appendix A.
[395] OMB Memorandum M-13-13, *Open Data Policy-Managing Information as an Asset* 1 (May. 9, 2013).
[396] *Id.*
[397] *Id.* at 6.
[398] *Id.* at 9.

data released by agencies."[399] It also requires agencies to consider the "'mosaic effect' of data aggregation," discussed at Section II.A.2.b)ii, which EPA does not acknowledge at all in the Proposal.[400]

EPA's *Open Government Plan 4.0* acknowledges that not all data is releasable to the public, even as it aims to "increase publicly accessible EPA data to support citizens' participation in government and promote transparency and accountability of Agency operations."[401] EPA states: "By providing *releasable* information in open and machine-readable formats, EPA enables the public and other organizations to better leverage the rich wealth of information available."[402] EPA's own *Open Data Policy* notes that it is important to develop "policies and processes to ensure that only appropriate data are released to the public and made available online."[403] To do so, EPA uses different "access levels" for different data sets, (public, restricted public and non-public) and notes that it may not be able to publicize data due to "law, regulation or policy, which address privacy, confidentiality, security or other valid restrictions."[404] EPA has not made clear that restricted access would satisfy the requirement of making information "publicly available." The Proposal seems to completely do-away with this multi-level, nuanced approach, imposing a blanket "publicly available" requirement for all studies EPA intends to rely on, despite obstacles to their release.

The Proposal turns away from EPA's *Scientific Integrity Policy*, which stresses "a firm commitment to evidence,"[405] endorses use of "the best available science"[406] and "[r]equire[s] reviews. . . regarding the content of a scientific product to be based only on scientific quality considerations."[407] The Proposal, on the other hand, inhibits use of sound scientific information and evidence by arbitrarily excluding science for reasons unrelated to its quality. While the policy "[r]ecognizes the value of independent validation of scientific methods"[408] and facilitating "the free flow of scientific information" by making information available "including access to data and non-proprietary models underlying Agency policy decisions,"[409] this is proposed as a flexible standard and an ideal to aspire to, not an absolute rule that takes priority over other competing interests—such as use of the best scientific information. As discussed more in Section VII.C this Administration has blatantly violated key aspects of the policy by silencing scientists and the dissemination of scientific information, which this Proposal seems aimed at continuing, directly undoing "EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information – uncompromised by political or other interference" and goal to communicate scientific findings openly and actively to the public.[410] By now placing

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[399] *Id.* at 10.
[400] *Id.* at 9-10.
[401] EPA, *Open Government Plan 4.0* 4 (Sept. 2016).
[402] *Id.* (emphasis added).
[403] EPA, *Open Data Policy Implementation Plan* 4, https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf.
[404] *Id.*
[405] EPA, *Scientific Integrity Policy* 3.
[406] *Id.* at 3-4.
[407] *Id.* at 4.
[408] *Id.*
[409] *Id.*
[410] *Id.* at 5.

"transparency" ahead of use of the best available science, aside from violating statutory requirements, EPA is changing its own policies and priorities and must justify this new position.

In footnote 2, EPA dubiously claims the Proposal is consistent with the *Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity* (Mar. 9, 2009).[411] Notably, the Memorandum specifies, "Except for information that is *properly restricted from disclosure* under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions."[412] Not only does the Memorandum provide no support for the notion that agencies should be barred from relying on studies where the underlying data is properly restricted from disclosure it additionally discusses disclosure only of findings and conclusions, not underlying data.

Thus, despite EPA's claims to the contrary, the Proposal marks a shift in policy that EPA has up to this point followed EPA arbitrarily fails to acknowledge this shift, to identify good reasons for the change, or to explain why EPA believes the proposed rule would be an improvement over current mechanisms utilized by EPA to ensure the integrity of EPA's actions.

2. EPA's Proposal fails to consider important implementation problems that existing EPA and federal government policies place at the forefront.

An agency rule is arbitrary and capricious if it "entirely failed to consider an important aspect of the problem."[413] EPA's Proposal completely fails to consider the numerous barriers that currently exist to making underlying data public. As highlighted in OMB and EPA policies, there is an understanding that the worthy goal of ensuring greater transparency of scientific information is in tension with other compelling, competing interests such as privacy and confidentiality. When these two are in tension, existing policies have recognized that this will prevent certain data from being publicly released—and that agencies still need to be able to use scientific information in these circumstances. Transparency goals should not override the ability of the agency to rely on otherwise valid scientific information as it goes about achieving its core mission. While the Proposal purports to take into account privacy and confidentiality concerns, it appears to do so by either grossly oversimplifying EPA's ability to address these concerns or by deeming all such information unusable—essentially completely failing to consider the problems of this approach.

OMB Circular A-130 recognizes that the values of openness, transparency, and allowing the free flow of information between the federal government and the public are important values, they must be contextualized. Thus, it cautions: "Promoting openness and interoperability, *subject*

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[411] 83 Fed. Reg. at 18,769 n. 2 ("If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking.")

[412] *Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity* (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009), https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09 (emphasis added).

[413] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

to applicable legal and policy requirements, increases operational efficiencies, reduces costs, improves services, supports mission needs, and increases public access to valuable Federal information."[414] Similarly it states: "The open and efficient exchange of scientific and technical Federal information, *subject to applicable security and privacy controls* and the proprietary rights of others, fosters excellence in scientific research and effective use of Federal research and development resources."[415] Circular A-130 makes clear that "[p]rotecting an individual's privacy is of utmost importance. The Federal Government shall consider and protect an individual's privacy throughout the information life cycle."[416] It requires that agencies recognize that "Federal information is managed by making information accessible, discoverable, and usable by the public to the extent permitted by law and *subject to privacy, security (which includes confidentiality), or other valid restrictions pertaining to access, use, dissemination, and disclosure*. . . ."[417]

Further, Circular A-130 requires agencies to "[l]imit the creation, collection, use, processing, storage, maintenance, dissemination, and disclosure of [personally identifiable information] to that which is legally authorized, relevant, and reasonably deemed necessary for the proper performance of agency functions" and "[t]o the extent reasonably practicable. . .reduce all [personally identifiable information] to the minimum necessary for the proper performance of authorized agency functions."[418]

The appendix to the Circular realizes that privacy protections require ongoing progress and:

> Emerging technologies and services may continue to shift the ways in which agencies acquire, develop, manage, and use information and technology. As technologies and services continue to change, so will the threat environment. Agency programs must have the capability to identify, respond to, and recover from current threats while protecting their information resources and the privacy of the individuals whose information they maintain.[419]

OMB Memorandum M-14-06 specifically lays out policies intended to help agencies make the most of "administrative data that cannot be made publicly available due to statutory, regulatory, or policy protections," for statistical purposes, including "activities typically characterized as research, evaluation, and analysis, as long as the focus of those activities is on reporting aggregate findings about a group."[420] It notes "[s]ome administrative data can be publicly released, whereas other administrative data cannot be released. . . [and] it is the case that both types of administrative data (public and nonpublic) can be useful for Federal statistical

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[414] OMB Circular A-130 at 3 (emphasis added).
[415] *Id.* at 4 (emphasis added).
[416] *Id.*
[417] *Id.* at 14 (emphasis added).
[418] *Id.* at 17.
[419] *Id.* at Appendix 1-1.
[420] OMB Memorandum M-14-06 at 6.

purposes," suggesting agencies should not abandon reliance on data not able to be publicly released.[421]

OMB Memorandum M-11-02 "strongly encourages Federal agencies to engage in coordinated efforts to share high-value data" but notes that in certain cases sharing data will contravene other compelling concerns and that federal agencies need to think about applicable privacy laws, regulations, and policies to "fully protect[] individual privacy" and preserve public trust.[422] Unlike the Proposal, it takes a more nuanced approach recognizing that sharing data is not always appropriate and should only be done "responsibly and appropriately."[423]

OMB recognizes that even when just sharing information among agencies, privacy concerns must be weighed against those benefits that agencies can achieve with sharing data: "Agencies should work together to determine what data sharing opportunities are desirable, feasible, and appropriate. In general, data sharing should only be pursued if the benefits outweigh the costs."[424]

OMB Memorandum M-10-06 also encourages "a plan for timely publication of the underlying data. . . in an open format and as granular as possible, consistent with statutory responsibilities and subject to valid privacy, confidentiality, security, or other restrictions."[425] The memorandum aims to achieve "transparency, participation, and collaboration,"[426] recognizing that not making data available does not deter those goals when there are valid concerns and the legitimacy of the data is not otherwise questioned.

EPA's *Draft Strategic Data Action Plan Version 1.0* similarly aims to work towards a more open government, and to increase the public's access to high quality data. However, the agency recognizes barriers to this goal, not applying the plan to "data resources containing Confidential Business Information (CBI) or sensitive data that are not available for public access."[427] In similarly recognizes that "[i]n order to protect the privacy and security of the public, businesses, and US Government staff and operations, some types of data may be deemed sensitive and will not be made public or published on Data.gov."[428]

These all highlight instances where EPA and OMB have recognized that privacy and confidentiality present ongoing concerns that are not easily addressed and that conflict with other aims of federal government. Yet, they recognize that protecting information in these cases is a valid path, and not making data public does not compromise the validity of the findings or

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[421] *Id.* at 2.
[422] OMB Memorandum M-11-02.
[423] *Id.*
[424] Memoranda 01-05 -- Guidance on InterAgency Sharing of Personal Data - Protecting Personal Privacy (Dec. 20, 2000), https://www.whitehouse.gov/wp-content/uploads/2017/11/2001-M-01-05-Guidance-on-Inter-Agency-Sharing-of-Personal-Data-Protecting-Personal-Privacy.pdf.
[425] OMB Memorandum M-10-06 on Open Government Directive at 8.
[426] *Id.* at 1.
[427] EPA, *Draft Strategic Data Action Plan Version 1.0* 3 (Mar. 2011) https://www.epa.gov/sites/production/files/documents/epa_sdap_v1.0.pdf.
[428] *Id.* at 14.

conclusions upon which the data is based and should prevent agencies from using those findings, conclusions, and data to inform their work. The Proposal provides no explanation for why EPA is now changing its view to a conflicting one, making the Proposal arbitrary.

III. The Proposed Rule's Peer Review Provisions Raise Numerous Concerns.

Proposed section 30.7 provides that "EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 Fed. Reg. 2664) and the exemptions described therein." This proposed provision generally appears to be designed to enshrine OMB's existing peer review requirements for "influential scientific information."[429]

Remarkably, the preamble to the proposed rulemaking lacks any explanation whatsoever for why EPA is proposing this new peer review requirement or what its impact might be. EPA has additionally not provided any information to suggest that EPA is not already following OMB's Peer Review Bulletin. EPA's lack of any supporting rationale or analysis frustrates the public's ability to provide meaningful comment on this provision,[430] and is itself a sign that this requirement is fundamentally arbitrary. In addition, the discussion below outlines several specific concerns with this proposed regulatory requirement.

A. EPA Has Failed to Consider the Costs of Making OMB Peer Review Requirements Judicially Enforceable.

The most obvious change wrought by EPA's incorporation of OMB's Peer Review Bulletin into EPA's regulations is that it apparently would make the OMB Peer Review requirements judicially enforceable. At present, OMB Peer Review Bulletin requirements are not judicially enforceable.[431] Rather, the Bulletin "specifically disclaims that its contents create any enforceable rights, thereby preserving the agency's discretion to interpret and apply" the Bulletin.[432] If EPA finalizes its proposed peer review rules, EPA may find itself subject to countless legal challenges to its regulations based on compliance with OMB Peer Review requirements. These additional legal challenges would come at a cost, including the financial cost of increased litigation as well as the cost to public health and the environment when unwarranted legal challenges lead to lengthy delays in implementation of needed regulatory protections. Given that EPA is already subject to OMB Peer Review requirements, it is unclear

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[429] OMB, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664, 2677 (Jan. 14, 2005) [Hereinafter: OMB Peer Review Bulletin].

[430] *See Connecticut Light & Power Co. v. Nuclear Regulatory Com.*, 673 F.2d 525, 530 (D.C. Cir. 1982) ("The purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process. If the notice of proposed rule-making fails to provide an accurate picture of the reasoning that has led the agency to the proposed rule, interested parties will not be able to comment meaningfully upon the agency's proposals."); *Honeywell Int'l, Inc. v. EPA*, 372 F.3d 441, 445, (D.C. Cir. 2004) ("Under the Administrative Procedure Act, a notice of proposed rulemaking must "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.").

[431] OMB Peer Review Bulletin § XII, 70 Fed. Reg. at 2674 ("This Bulletin is intended to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.").

[432] *Family Farm Alliance v. Salazar*, 749 F.Supp. 2d 1083, 1095 (E.D. Ca. 2010).

whether the proposed regulation would provide any new benefits in terms of ensuring that EPA's regulations are based on valid and unbiased science. Yet the administrative record for this proposed rulemaking is devoid of any EPA analysis of the costs and benefits of making the existing peer review requirements judicially enforceable. EPA must carefully evaluate the anticipated costs and benefits from these proposed regulatory requirements and provide a reasoned explanation for why they are needed.

B. EPA Must Clarify that Studies that Have Already Been Adequately Peer-Reviewed by Third Parties Need Not be Re-Reviewed by EPA.

Because proposed section 30.7 expressly incorporates the OMB Peer Review Bulletin "and the exemptions described therein," it appears that EPA intends to incorporate the OMB Peer Review Bulletin provision providing that "agencies need not have further peer review conducted on information that has already been subjected to adequate peer review."[433] However, there is some ambiguity due to language in proposed section 30.7 instructing that EPA must "ask peer reviewers to articulate the strengths and weaknesses of EPA's justifications for the assumptions applied and the implications of those assumption for the results." Obviously, peer review conducted prior to EPA's reliance on a study would not have involved review of the strengths and weaknesses of EPA's justifications. If EPA were required to re-peer review all influential scientific information, this rulemaking would burden EPA with needless and significant costs that likely would bring many EPA rulemakings to a standstill, preventing EPA from fulfilling its statutory mission of protecting public health and the environment. To prevent this from happening, EPA must clarify that the proposed rule will not supplant EPA's existing authority under the OMB Peer Review Bulletin not to conduct further peer review where information has already been subject to adequate peer review—and that such prior peer review is not subject to the requirement in proposed section 30.7 that reviewers consider the strengths and weaknesses of EPA's justifications.

C. EPA Must Clarify the Intent of the Exemption Provision with Respect to Peer Review Requirements and Confirm that the OMB Peer Review Bulletin's Waiver Provision Would Remain in Effect for EPA.

EDF does not support the peer review provisions for the reasons detailed in this section, but if EPA moves ahead with these proposed provisions, EPA must revise the proposed regulatory language to clarify that the waiver authority provided by the OMB Peer Review Bulletin—which OMB itself has emphasized "ensure[s] needed flexibility"—would remain in effect for EPA even if EPA finalizes the proposed peer review regulations.[434]

Proposed section 30.9(b) provides that the Administrator may grant an exemption from the peer review requirements if he or she determines that "[it] is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality for Peer Review (70 FR 2664), Section IX." Oddly, however, only two of the seven enumerated exemptions in Section IX of the OMB Peer

[433] OMB Peer Review Bulletin, 70 Fed. Reg. at 2675.
[434] OMB Peer Review Bulletin, 70 Fed. Reg. at 2673.

Review Bulletin pertain to feasibility—Exemption 1 governing "national security, foreign affairs, or negotiations involving international trade or treaties" and Exemption 3 governing time-sensitive health or safety disseminations.[435] If EPA decides to finalize peer review requirements, EPA must amend its proposed regulation to clarify that all of the exemptions set forth in section IX of the OMB Peer Review Bulletin remain in effect regardless of whether they pertain to feasibility. Furthermore, EPA must clarify what, if any, additional effect is intended by the exemption provision in proposed section 30.9.

Additionally, EPA must amend the proposed rule to confirm that the "Deferral and Waiver" provision set forth in Section VIII of the OMB Peer Review Bulletin remains in effect for EPA. That provision provides: "The agency head may waive or defer some or all of the peer review requirements of Sections II and III of this Bulletin where warranted by a compelling rationale. If the agency head defers the peer review requirements prior to dissemination, peer review shall be conducted as soon as practicable." [436] OMB explained that this provision "ensure[s] needed flexibility in unusual and compelling situations not otherwise covered by the exemptions in the Bulletin before information is disseminated."[437] If EPA were to finalize the "exemption" language in proposed section 30.9(b) without clarification, it is possible that it could be read to encompass the entirety of the Administrator's ability to grant exemptions, supplanting Section VIII of the OMB Peer Review Bulletin.

D. EPA Must Clarify How the Proposed Rule Would Impact EPA's Existing Peer Review Handbook.

EPA's Peer Review Handbook incorporates the provisions of OMB's Peer Review Bulletin.[438] In the Handbook, EPA confirms that it "conducts peer review of its products in accordance with the guidance in the OMB Peer Review Bulletin."[439] However, the EPA Peer Review Handbook adds details and specific procedures that are not present in the OMB Peer Review Bulletin.

Surprisingly, EPA's proposed peer review regulations do not even mention EPA's Peer Review Handbook, let alone explain how the new proposed regulations would impact EPA's compliance with the Handbook. For example, EPA's Handbook specifies "exemption criteria" in Section 3.3.[440] EPA must clarify whether anything in the proposed peer review regulation would supplant instructions in the Peer Review Handbook, and if so, provide a reasoned explanation for the change. Likewise, EPA must explain the role of the Peer Review Handbook going forward in administering peer review requirements.

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[435] OMB Peer Review Bulletin, 70 Fed. Reg. at 2674.
[436] OMB Peer Review Bulletin, 70 Fed. Reg. at 2673.
[437] OMB Peer Review Bulletin, 70 Fed. Reg. at 2673.
[438] U.S. EPA, *Science and Technology Policy Council Peer Review Handbook*, 4th Ed. (2015), https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf. [Hereinafter: EPA Peer Review Handbook].
[439] EPA Peer Review Handbook at 26.
[440] EPA Peer Review Handbook at 44-45.

IV. The Proposal Would Impose Arbitrary and Inappropriate Methods for Assessing Health Risks

A. EPA's Proposal Seeks to Undermine Key Scientific and Public Health Tenets Relating to Dose-Response and the Use of Defaults.

The proposed rule asserts that a broad interest of the current Administration is to "ensure that the data and models underlying scientific studies that are pivotal to. . . regulatory action are available to the public"[441] and to "change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis."[442] However, the Proposal specifies a particular interest and initial focus on "dose response data and models" as evident throughout the preamble and proposed regulatory provisions.

Dose-response studies are a critical element of risk assessments for toxicants including air pollutants. Assessment of a toxicants risks typically proceeds through a four-step process: 1) hazard identification, 2) dose-response assessment, 3) exposure assessment, and 4) risk characterization.[443] Dose-response assessment describes the relationship between exposure to a toxicant and observed effect on human or ecological receptor. EPA provides the following description of dose-response on its website: "Dose-Response Assessment...characterizes the quantitative relationship between chemical exposure and each credible health hazard. These quantitative relationships are then used to derive toxicity values."[444] Dose-response plays a central role in the evaluation of chemical risks as it provides the characterization of the potency or effect size of the toxicant. In other words, dose-response assessment is used to determine the levels of exposure at which adverse effects will occur and thus informs what risk management actions should be taken to protect human and ecological health. Dose-response assessments are commonly used to derive chemial toxicity values. The lower a substance's toxicity value the greater its potency and the less exposure is necessary for an effect to occur.

EPA reveals the underlying motivation behind its interest in transparency of dose-response data and models on page eight of the Proposal, where it states:

> In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies

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[441] Proposed Rule, 83 Fed. Reg. at 18769-70.
[442] Proposed Rule, 83 Fed. Reg. at 18770.
[443] EPA, *Conducting a Human Health Risk Assessment*, https://www.epa.gov/risk/conducting-human-health-risk-assessment (last accessed Aug. 16, 2018).
[444] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last accessed Aug, 16, 2018).

> that explore: A broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.[445]

This excerpt raises several troubling and erroneous concepts that are contrary to core scientific tenets and best practices in chemical hazard and risk assessment as discussed extensively in a seminal 2009 report by the National Academies (Academies): *Science and Decisions: Advancing Risk Assessment (Science and Decisions)*.[446] The report was requested and sponsored by EPA's National Center for Environmental Assessment and was developed over a three-year period by a 15-member committee that included state environmental agencies, non-governmental organizations, industry, and academic institutions. The committee was specifically tasked with "developing scientific and technical recommendations for improving risk analysis approaches used by EPA, including providing practical improvements that EPA could make in the near term (2-5 years) and in the longer term (10-20 years)."[447] The report has been cited over 400 times in the scientific literature.

The Proposal fails to discuss these best practices for risk assessment, much less provide any persuasive reason for departing from them. The Proposal provides no support for its assertion that there is "growing empirical evidence" of nonlinearity in dose-response relationships; fails to acknowledge or contend with the National Academies' finding that non-threshold dose-response relationships are common for toxicants, and should be assumed as a default; fails to discuss the well-known rationales put forward by the National Academies for using default models; and irrationally prioritizes consideration of studies that employ a wide range of dose-response models, without any consideration for whether those alternative dose-response models are appropriate for risk assessment. Alarmingly, the Proposal offers no analysis of how the proposed requirements to consider threshold-response relationships and avoid default models would further the protection of human health and the environment—and gives no indication that the Agency has considered whether its proposed approach affords appropriate protection for the public in evaluating the risks of dangerous pollutants and toxicants. The proposed requirement is irretrievably arbitrary and unjustified, and must be withdrawn.

1. The proposal arbitrarily dismisses linear (i.e., non-threshold) dose-response relationships.

EPA makes a blanket assertion that "there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects" without any evidentiary basis.[448] In contrast, in *Science and Decisions*, the Academies discussed at length the

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[445] Proposed Rule, 83 Fed. Reg. at 18770.
[446] National Academies, *Science and Decisions: Advancing Risk Assessment* (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.
[447] *Id.*
[448] Proposed Rule, 83 Fed. Reg. at 18770.

evidence for the opposite. Namely, non-linear dose-response relationships—that is the existence of thresholds of chemical exposure below which effects are not expected to be observed—is the exception rather than the rule when considering background exposures, co-exposures, variability across the diverse population and other considerations. The *Science and Decisions* report notes:

> . . . [A]n individual's risk from exposure to an environmental chemical is determined by the chemical itself, by concurrent background exposures to other environmental and endogenous chemicals that affect toxicity pathways and disease processes, and by the individual's biologic susceptibility due to genetic, lifestyle, health, and other factors. How the population responds to chemical insults depends on individual responses, which vary among individuals.[449]

In this regard, it is important to note that risk assessments are typically designed to estimate incremental risk in the population due to exposure to a single hazard. As discussed by the Academies, individual risk is determined by both the chemical exposure and an individual's unique circumstance of factors (e.g., co-exposures and susceptibilities). Cancer incidence in the population illustrates the significance of these additional factors in considering actual individual risk to a particular chemical exposure. Individual lifetime risk of developing cancer is 1 in 3, and 1 in 5 for dying from cancer,[450] indicating a substantial population baseline risk resulting from a large number of exposures and other risk factors. Assuming that there is somehow a threshold for everyone cannot be supported by the evidence. Therefore, given that the mission of EPA is to protect public health, the linear approach is most appropriate unless there is strong evidence in favor of an alternative as recommended in *Science and Decisions*.

EPA currently approaches risk assessment of 1) carcinogens and 2) noncarcinogens and carcinogens "acting through an MOA [mode of action] considered nonlinear at low doses"[451] separately—applying a linear dose-response framework for the former and a non-linear dose-response framework for the latter. The Academies strongly argued against this arbitrary distinction and recommended a uniform *linear* approach to the assessment of all chemicals. Indeed, for carcinogens purported to have a non-linear MOA, the Academies indicated:

> . . . omissions in this overall approach for low-dose nonlinear carcinogens could yield inaccurate and misleading assessments. . . . [T]he current EPA practice of determining "nonlinear" MOAs does not account for mechanistic factors that create linearity at low dose. The dose-response relationship can be linear at a low dose when an exposure contributes to an existing disease process. Effects of exposures that add to background processes and background endogenous and exogenous exposures can lack a threshold if a baseline level of dysfunction occurs without the toxicant and the toxicant adds to or augments the background process. Thus, even small doses may have a relevant biologic effect. That may be difficult

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[449] National Academies, *Science and Decisions: Advancing Risk Assessment* 135 (2009).
[450] American Cancer Society, Lifetime Risk of Developing or Dying From Cancer, https://www.cancer.org/cancer/cancer-basics/lifetime-probability-of-developing-or-dying-from-cancer.html (last revised Jan. 4, 2018).
[451] National Academies, *Science and Decisions: Advancing Risk Assessment* 129 (2009).

> to measure because of background noise in the system but may be addressed through dose-response modeling procedures. Human variability with respect to individual thresholds for a nongenotoxic cancer mechanism can result in linear dose-response in the population.[452]

Similarly, for noncarcinogens, the Academies indicated that "noncarcinogens can exhibit low-dose linearity, for example, when there is considerable interindividual variability in susceptibility and each individual has his or her own threshold, especially when an underlying disease (such as cardiopulmonary disease) can interact with the toxicant (such as particulate matter [PM] or ozone)."[453]

The Academies ultimately and definitively recommended that "cancer and noncancer responses be assumed to be linear as a default. . . [and that] [a]n alternative analytic option. . . is available for cases in which it can be shown that background is unlikely to be an important contributor to risk, according to the recommended evaluation of MOAs and background."[454]

2. The proposal improperly dismisses defaults.

EPA's Proposal also indicates an interest and intent to move away from "default models, without consideration of alternatives or model uncertainty" which purportedly "can obscure the scientific justification for EPA actions."[455] Here, EPA demotes and ignores the purpose of science-based defaults, in suggesting that they "obscure the scientific justification for EPA actions" while simultaneously encouraging routine application of model alternatives without meaningful justification or substantiation.

Again, EPA's Proposal deviates significantly from the recommendations in *Science and Decisions* where the Academies wrote,

> [D]efaults need to be maintained for the steps in risk assessment that require inferences or to fill common data gaps. Criteria are needed for judging whether, in specific cases, data are adequate to support a different inference from the default (or whether data are sufficient to justify departure from a default).[456]

The Academies further recommended that 1) "EPA should continue and expand use of the best, most current science to support or revise its default assumptions," 2) "work toward the development of explicitly stated defaults to take place of implicit or missing defaults," and 3) that "departure [from defaults] should occur only when the evidence of the plausibility of alternatives is clearly superior to the evidence of the value of the default."[457] These recommendations underscore and reaffirm the role of defaults, and make clear that deviations

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[452] National Academies, *Science and Decisions: Advancing Risk Assessment* 129-30 (2009).
[453] National Academies, *Science and Decisions: Advancing Risk Assessment* 131 (2009).
[454] National Academies, *Science and Decisions: Advancing Risk Assessment* 180 (2009).
[455] Proposed Rule, 83 Fed. Reg. at 18770.
[456] National Academies, *Science and Decisions: Advancing Risk Assessment* 207 (2009).
[457] *Id.*

from defaults are to be considered carefully, on a case-by-case basis, and only when adequately justified.

3. The Proposal arbitrarily promotes studies that include a variety of dose-response models.

EPA's Proposal promotes the use of studies that explore a variety of dose-response models. Use of dose-response models to estimate pollutant or chemical risk should generally address issues such as goodness-of-fit, confidence bounds around predicted risks, biological plausibility, and sensitivity of the prediction to untested assumptions.[458]

However, giving higher weight to studies that use a wide range of models just because they use a wide range models is wholly inappropriate, arbitrary, and without scientific or public health justification. In fact, it creates a perverse incentive to apply multiple models to data without regard to appropriateness of fit and underlying assumptions (among other key considerations), and importantly, without regard to public health and ecological protection. It is worth noting that nowhere in the Proposal has the agency articulated how this requirement would further its primary mission and purpose of protecting human health and the environment.

There are numerous dose-response analyses that could be applied to any data set. Any analysis of the data assumes an underlying statistical distribution of the data, models for mean response, variance structures, shapes, and other data fit considerations that are subject to choice in the formal analysis. Scientists have historically used a reduced set of science-based, empirically supported models for specific types of data that have obtained widespread acceptance. EPA's specification of various types of modeling approaches the agency should consider ignores this reality.

4. The proposed rule provides no justification for codifying scientific approaches into regulation.

The proposed rule's provisions addressing dose-response models are inappropriate for the numerous reasons discussed in this section. They also unnecessarily and inappropriately memorialize highly complex and technical scientific issues into regulation—a generally frowned approach given the inherently evolving nature of science. These issues are more appropriately dealt with in guidance, a more flexible vehicle better equipped for adapting to new scientific understanding and in this way supporting use of best available science.

V. EPA Fails to Adequately Consider Costs and Benefits of the Proposal.

It is arbitrary and capricious to "'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (quoting *State Farm*, 463 U.S. at 43). As in *Michigan*, failure to consider the costs and benefits of a regulation where there is no statutory bar to doing so is arbitrary and capricious.

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[458] Nat'l Research Council, Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment (2006), https://www.nap.edu/catalog/11688/health-risks-from-dioxin-and-related-compounds-evaluation-of-the.

The proposed rule entirely fails to comply with the requirements of non-arbitrary-and-capricious rulemaking because it fails to disclose, much less analyze or consider, any of the costs of the rule; barely discusses and does not analyze or quantify the benefits; does not provide any *reasoned* explanation of why the benefits of the rule justify its costs; and does not consider potential alternatives. The Proposal's discussion of costs and benefits is a scant two paragraphs[459] (and was apparently not included at all in the version sent to the Office of Management and Budget).[460] The proposed rule begins by conclusorily asserting that "EPA believes the benefits of this proposed rule justify the costs."[461] It then briefly discusses the perceived benefits, incorrectly suggesting that the National Academy of Sciences shares EPA's view by citing to a publication that discusses both *risks* and opportunities of expanding access to research data, and does not discuss *at all* the costs and benefits of *ignoring* relevant science in regulatory decisionmaking.[462] It then merely states that the "action should be implemented in a cost-effective manner," citing vaguely to "recent activities of the scientific community and other federal agencies" without any concrete examples or analysis.[463] The preamble's discussion emphasizes that the Proposal does not compel EPA to make information available where it concludes that doing so is not possible, but omits that if compliance is not possible, EPA will not consider the study, which has its own costs. It then concludes by citing the working paper of the Mercatus Center[464] that baldly asserts that improvements in reproducibility "can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits."[465] Setting aside the lack of substantiation for this assertion, it entirely omits situations in which costs and benefits are wrongly estimated because the relevant science is not used—and the costs that would be imposed on society if EPA inadequately protects communities from harmful pollution or toxic exposures.

Indeed, the Proposal *nowhere* discusses its significant costs in either quantitative or qualitative terms, costs that have actually been examined by independent organizations, and that are susceptible to analysis. If the Proposal is truly "designed to provide a mechanism to increase access to" data "in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants," 83 Fed. Reg. at 18,770, then it will have significant costs. And if, as it appears, the Proposal's true "mechanism" is excluding science from regulatory decisionmaking, its costs will be even greater in the form of insufficiently protective regulations.

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[459] Proposed Rule, 83 Fed. Reg. at 18,772.

[460] *Compare*, EO 12866 Proposal 2080-AA14 OIRA Conclusion Document (Docket ID. No. EPA-HQ-OA-2018-0259-0006) *with* EO 12866 Proposal 2080-AA14 OIRA Review Start Document (Docket ID. No. EPA-HQ-OA-2018-0259-0007).

[461] Proposed Rule, 83 Fed. Reg. at 18,772.

[462] *Id.*

[463] *Id.*

[464] For a proposal allegedly aimed at increasing transparency, it is notable that EPA does not disclose that Charles Koch—an outspoken opponent of public health protections who stands to gain financially from deregulation—is a board member of the Mercatus Center. Mercatus Center, *Charles Koch*, https://www.mercatus.org/charles-koch (last accessed: Aug. 1, 2018).

[465] Proposed Rule, 83 Fed. Reg. at 18,772.

If it were not possible to quantify and monetize any of the costs, which is not the case here as discussed below, EPA would still be required under E.O. 12866 and the requirements of rational rulemaking to identify and discuss the qualitative costs of this Proposal. It is inherently irrational for an agency to take an action without any consideration of any costs, disadvantages or negative effects of that action. The qualitative costs of this Proposal include the costs to researchers of actions they must undertake to protect the confidentiality of patient and subject data, as well as to compile and make public their raw data, and the potential loss of subjects (and attendant damage to research efforts and results) due to confidentiality concerns. There are also various costs to the agency of administering the regulation, which include contacting researchers, gathering data, ensuring that patient confidentiality and confidential business information are not disclosed. Additional costs could also be incurred through conducting any additional peer reviews required by proposed section 30.7 and any additional analyses imposed by proposed section 30.6's requirement that "EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions." Most importantly, there are potentially huge costs of regulating without using the relevant science merely because the underlying raw data is not publicly available. If studies supporting a stronger standard are excluded and EPA can therefore only justify a weaker requirement that leaves large numbers of people at risk of health effects from a pollutant, pesticide, or chemical, then this Proposal could impose enormous costs for each insufficiently protective regulation.[466] Yet the Proposal fails even to mention these costs, let alone discuss their scope and significance.

In addition, many of these costs can be quantified and monetized, but EPA has neither attempted to do so nor explained why it could not. For example, EPA has extensive information available to it on what the agency would need to do to implement this Proposal and how much those activities would cost. In fact, EPA already gathered much of this data and provided it to the Congressional Budget Office for use in estimating the costs of a similar (though not identical) proposal from Congress, the HONEST Act. With respect to the Congressional proposal, CBO concluded, just with respect to the costs to EPA, that "based on information from the EPA and other federal agencies, as well as organizations and researchers in the scientific community that publish in peer-reviewed journals," EPA "could spend between a few million dollars per year to more than one hundred million dollars per year … to ensure that data and other information underlying studies are publicly available in a format sufficient to allow others to substantially reproduce the results of studies."[467] In the 2017 estimate, CBO concluded that "[i]f the EPA continued to rely on as many scientific studies as it has used in recent years … then CBO

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[466] In footnote 3 of the Proposal, Proposed Rule, 83 Fed. Reg. at 18,769, EPA suggests that the studies underlying the NAAQS for particulate matter, at issue in the case cited—*Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 358 (D.C. Cir. 2002)—are an example of data the agency would be "preclude[d]" from using in the future. The benefits of these NAAQS included up to $75,100 million in annual benefits from avoided cases of mortality in 2010 alone for a partial attainment scenario. National Research Council (US) Committee, *Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations*, 43
National Academies Press (2002), https://www.ncbi.nlm.nih.gov/books/NBK221028/.

[467] Congressional Budget Cost Estimate for H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (Mar. 29, 2017) ("2017 CBO Estimate"); *see also* Congressional Budget Office Cost Estimate, S. 544, Secret Science Reform Act of 2015 (June 5, 2015) (estimating that another similar congressional proposal would cost up to $250 million per year).

estimates that the agency would need to spend at least $100 million dollars per year to upgrade the format and availability of those studies' data," "on average, $10,000 per scientific study."[468] Such costs would cover the costs of "obtaining all the underlying data used in a study, reviewing the data to address any confidentiality concerns, formatting the data for public access, providing access to the computer codes and models used in the study's analysis, and providing descriptions and documentation on how to access the data."[469] Notably, this does not include the cost to researchers to engage in this effort. As Deputy Assistant Administrator Nancy Beck noted, during the development of the Proposal, requiring "a huge amount of data to be submitted to the agency" would "be incredibly burdensome" and "not practical."[470]

Even the Mercatus working paper—apparently the only thing EPA relied upon in discussing the costs and benefits of the Proposal, 83 Fed. Reg. 18,772 n. 24, notes, with respect to the HONEST Act, that "[t]he cost of providing access to data has been one of the primary concerns about requiring access to data used by the federal government."[471] Far from concluding, as the Proposal suggests, an increase in net benefits from greater reproducibility, the Mercatus working paper simply explained a figure the authors were suggesting could be calculated (the point where net benefits would be positive); the authors do not themselves calculate the benefits, and admit that their "estimates of the benefits of public access to data supporting federal regulatory decisions fall short of proving that the benefits outweigh the associated costs."[472] And while the Mercatus working paper disagrees with CBO's cost estimates, it does not argue that that requiring access to data is cost-less; indeed, it discusses the "costly activities and services that need to be performed," including activities related to "data collection and data accessibility."[473] According to that working paper, data collection requires "correspond[ing] with researchers and publishers to obtain the data, review[ing] the data for confidentiality concerns, format[ting] the data for public access, publicly post[ing] the computer code and models used in each study's analysis, and provid[ing] descriptions and documentation on how to obtain the date."[474] Data accessibility requires "computer processing services to construct and maintain data bases to store study-related information."[475] While the actual calculations put forward by the Mercatus working paper appear faulty (for example, it entirely omits the cost to researchers to compile and make their data public, does not include the costs of ensuring patient privacy is protected,[476] and makes assumptions about the similarity of a chemical manufacturer collecting its own studies and EPA collecting and disseminating information of other researchers), the working paper at least acknowledges that there are costs, something EPA's Proposal completely ignores.

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[468] 2017 CBO Estimate at 3.
[469] *Id.*
[470] Email from Nancy Beck to Richard Yamada (Jan. 31, 2018 2:51 PM).
[471] Mercatus Working Paper 19.
[472] *Id.* at 27-29.
[473] *Id.* at 20.
[474] *Id.*
[475] *Id.* at 20-21 (quoting CBO, "Cost Estimate, S. 544, Secret Science Reform Act of 2015," June 5, 2015).
[476] For example, this may require special archiving and access arrangements to limit data sharing, such as those in NIH data sharing plans, which NIH requires only for studies that receive more than $500,000 in federal funding in a year. NIH, NIH Data Sharing Policy and Implementation Guidance, https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm (last accessed Aug. 16, 2018).

Nor does the proposed rule disclose the cost—highlighted on the very first page of a National Academy of Sciences (NAS) report on data access—that "perceived risks to privacy and confidentiality reduce survey participation," a cost that the NAS explains is "borne out by research."[477] NAS explains that this "threatens the research enterprise itself, because concerns about privacy and confidentiality are among the reasons often given by potential respondents for refusing to participate in surveys, and those concerns have been shown to affect behavior as well.[478] The NAS panel emphasized: "Any confidentiality breach that became known would be likely to heighten such concerns and, correspondingly, reduce survey response rates. Efforts to increase researchers' access to data must, therefore, take into account the need to avoid increasing the actual and perceived risks of confidentiality breaches."[479] The Proposal does not so much as discuss this potential cost.

This confidentiality risk has a further cost: it affects the quality of the data collected. As the NAS explained:

> The reason for confidentiality pledges and for stringent procedures to prevent disclosure is that they improve the quality of data collected from individuals, households, and firms. It is essential that respondents believe they can provide accurate, complete information without any fear that the information will be disclosed inappropriately. Indeed, if the information was disclosed, harm might come to an individual respondent.[480]

The Proposal's only acknowledgment of this complex problem and cost is its statement that "EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government."[481] Remarkably, EPA does not cite a single example of these common solutions, citing only vaguely to "examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau" and some hyperlinks not in the Proposal added to the docket almost a month into the comment period.[482] Accordingly, not only does the Proposal include no analysis of these alleged solutions and their costs and benefits, it does not even explain what the solutions are that EPA believes address this concern.

And if EPA complies with the regulation *not* by spending the money to make data publicly available, and if the research community does not bear those costs itself, *see* 83 Fed. Reg. at 18,770-71 ("Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections."), then it appears that EPA would simply ignore studies that do not comply with the regulation. *See* 83 Fed. Reg. at 18,769 n. 3 ("EPA is proposing to exercise its discretionary authority to establish a

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[477] National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, vii National Academies Press (2005).
[478] *Id.* at 51; *see also id.* at 52-54 (describing the research supporting this risk).
[479] *Id.* at 51.
[480] *Id.*
[481] 83 Fed. Reg. at 18,770.
[482] *Id.*

policy that would preclude it from using such data in future regulatory actions."). That course of action has its own significant costs, and EPA provides no analysis in the Proposal of the magnitude of studies that it has previously relied upon that it could no longer rely upon in regulating. *See* 2017 CBO Estimate ("EPA officials have explained to CBO that the agency would implement H.R. 1430 with minimal funding and generally would not disseminate information for the scientific studies that it uses to support covered actions. That approach to implementing the legislation would significantly reduce the number of studies that the agency relies on when issuing or proposing covered actions…."). As the SAB noted in its May 12, 2018 letter, "[t]he proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs. Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits."[483]

Likewise, EPA has included only a cursory mention of the expected qualitative benefits of the Proposal, with no discussion of the anticipated likelihood, scope, or impact of the suggested benefits, let alone any effort to quantify them, much less monetize them. EPA simply assumes that the Proposal will "improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing an exploration of key data sets" without any analysis or evidence. In fact, as we have explained, the likely outcome of the Proposal is that it will degrade the data and scientific quality of the Agency's actions by ignoring relevant science simply because the underlying data is not publicly available. Moreover, EPA's finding is not consistent with the conclusions of the National Academies, as the Proposal suggests. As also explained above, the NAS report highlighted both the risks and benefits of making data publicly available and nowhere concluded that there were benefits to excluding data from the agency's regulatory decisions simply because the underlying data was not publicly available. Nor does the agency analyze how likely its Proposal is to actually facilitate expanded data sharing, and its main aim appears to be excluding science as it does not actually provide any funding, mechanisms, or best practices for sharing data.

It is more than ironic that EPA claims—without any data or analysis—that its Proposal will increase the net benefits of other regulations while it does nothing to actually consider the costs and benefits of the Proposal itself. Moreover, there is no reason to think that excluding relevant science merely because the underlying data is not publicly available would increase the net benefits of a regulation. For example, it appears that under the proposed rule EPA would exclude a peer-reviewed, published study whose conclusion had been reproduced based upon numerous different datasets (and whose underlying data, though not publicly available, had been reevaluated by outside experts), while including a study that had had no peer review, was not published, had no corroborating studies, and had not actually been replicated or reproduced, merely because the underlying data was made publicly available. That is simply not a recipe for more accurate decisionmaking.

The proposed rule also violates the APA and other statutes' requirements for reasoned decisionmaking by failing to consider any alternative approaches, much less their costs, here. This is particularly irrational in this context where it appears that many of the benefits sought by

[483] Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons 3 (May 18, 2018).

EPA could be largely achieved with much less burdensome and costly approaches. A critical element of reasoned decision making is consideration of alternatives which are congruent with agencies' statutory responsibilities and objectives. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48, 50 (1983) (safety agency acted arbitrarily in failing to consider alternative safety measures after rejecting passive restraints). EPA failed to consider other methods to ensure scientific robustness at the agency. For example, the SAB letter notes that "[t]he proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods."[484] The Proposal does not consider any alternatives to ensuring that studies are reliable even where the underlying data cannot be made public because of privacy or other concerns.

Furthermore, by failing to consider costs and benefits, the Proposal contravenes Executive Order 12866. Executive Order 12866 requires agencies to assess the costs and benefits of proposed regulations and propose or adopt a regulation only upon a reasoned determination that the benefits justify the costs.[485] For "significant regulatory actions," like the proposed rule, 83 Fed. Reg. at 18,772, the agency must provide:

> (i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;
> (ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and
> (iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.[486]

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[484] *Id.* at 4 (pointing to the Health Effects Institute re-analysis of the Harvard Six Cities and American Cancer Society epidemiological studies).
[485] Exec. Order 12866 § 1(b)(6)-(7) (Oct. 4, 1993).
[486] Exec. Order 12866 § 6(a)(3)(C).